

RECEIVED
CENTRAL FAX CENTER

SEP 15 2006

CROMPTON | SEAGER | TUFTE | LLC
Patent, Trademark & Copyright Attorneys1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Phone 612.677.9050
Fax 612.359.9349*Resubmission
- due to all pages
not received
9/15/06***FAX TRANSMISSION**TO: Commissioner for Patents
Attn: Examiners M. Hayes and K. Sirmons
Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450DATE: September 15, 2006
FROM: David M. CromptonOUR REF: 1001.1566101
TELEPHONE: 612-677-9050

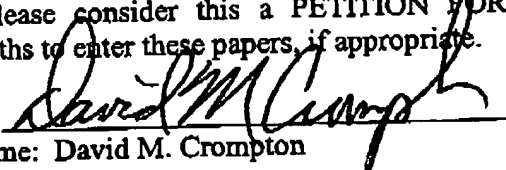
Total pages, including cover letter: 80

PTO FAX NUMBER: 571-273-8300

If you do NOT receive all of the pages, please telephone us at (612) 677-9050, or fax us at (612) 359-9349.

Title of Document(s) Transmitted: AMENDED APPEAL BRIEF INCLUDING
APPENDICES A-CApplicant: Jill McFadden et al.
Serial No.: 09/097,023
Filed: June 12, 2008
Group Art Unit: 3767
Our Ref. No.: 1001.1566101
Confirmation No.: 2472
Customer No.: 28075

It is believed that no fees are due at this time. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413. Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate.

By: 
Name: David M. Crompton
Reg. No. 36,772

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.


Name: Kathleen L. BoekleySeptember 15, 2006
Date

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

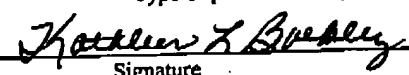
RECEIVED
CENTRAL FAX CENTER

SEP 15 2006

In re: Jill McFadden et al. Confirmation No.: 2472
Serial No.: 09/097,023 Examiner: M. Hayes and K. Simmons
Filing Date: June 12, 1998 Group Art Unit: 3767
Docket No.: 1001.1566101 Customer No.: 28075
For: CATHETER WITH KNIT SECTION

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED APPEAL BRIEF UNDER 37 C.F.R. § 41.37

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (1)(B))	
I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office at <u>703-872-9306</u> on the date shown below.	
<u>Kathleen L. Bockley</u>	
Type or print name of person signing certification	
	<u>September 15, 2006</u>
Signature	Date

Dear Sir:

Pursuant to 37 C.F.R. § 41.37(d), Appellants hereby submit this Amended Appeal Brief in furtherance of the Notification of Non-Compliant Appeal mailed August 22, 2006, regarding the Appeal Brief filed on May 16, 2005. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

RECEIVED
CENTRAL FAX CENTER

SEP 15 2006

TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST	4
II.	RELATED APPEALS AND INTERFERENCES	4
III.	STATUS OF CLAIMS	4
IV.	STATUS OF AMENDMENTS	5
V.	SUMMARY OF CLAIMED SUBJECT MATTER	6
VI.	GROUND OF REJECTION TO BE REVIEWED ON APPEAL	13
VII.	ARGUMENT	14
A.	<i>Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 are patentable over the §102(b) rejection relying on JP 05-220225 supplemented by the Examiner's reliance of Samson, U.S. Patent No. 5,702,373, for description of the JP 05-220225 document</i>	<i>14</i>
	1. <i>The Examiner improperly relies on the JP 05-220225 document</i>	<i>14</i>
	2. <i>JP 05-220225 fails to teach or suggest each and every element and structural limitation of the claimed invention</i>	<i>15</i>
	3. <i>The definition given to the term "knitted" as used in the current application is dissimilar to that used in JP 05-220225</i>	<i>17</i>
	4. <i>The Examiner's inherency argument is flawed</i>	<i>19</i>
B.	<i>Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 are patentable over the §102(e) rejection relying on Leoni, U.S. Patent No. 5,772,681 ...</i>	<i>20</i>
	1. <i>Leoni fails to teach or suggest each and every element and structural limitation of the claimed invention</i>	<i>20</i>
	2. <i>The Examiner's inherency argument is flawed</i>	<i>22</i>
C.	<i>Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, and Cox, U.S. Patent No. 5,257,974</i>	<i>23</i>
	1. <i>A reference used to establish a prima facie case of obviousness must be analogous art</i>	<i>23</i>

2. There is no suggestion or motivation to combine the teachings of Cook with the teachings of Cox.....	23
i. The references teach away from one another	24
ii. Modification of one reference with the teachings of the other reference would render the modified apparatus unsatisfactory for its intended purpose	25
D. Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, Cox, U.S. Patent No. 5,257,974, and Leoni, U.S. Patent No. 5,772,681	27
E. Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, and Andersen et al., U.S. Patent No. 5,674,276	27
F. Claims 17, 22, 44 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, and Jang et al., U.S. Patent No. 4,898,591	28
G. Claims 17, 22, 44 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, Cox, U.S. Patent No. 5,257,974, and Jang et al., U.S. Patent No. 4,898,591	29
H. Conclusion	30
VIII. CLAIMS APPENDIX.....	31
IX. EVIDENCE APPENDIX.....	37
X. RELATED PROCEEDINGS APPENDIX.....	38

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Target Therapeutics, Inc., a corporation organized and existing under and by virtue of the laws of Delaware, and having a business address of 47201 Lakeview Boulevard, Fremont, CA 94537. An assignment from the inventors, Jill M. McFadden, Earl Bardsley and Robert Garabedian, conveying all right, title and interest in the invention to Target Therapeutics, Inc. has been recorded at Reel 9458, Frame 0534.

II. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal was previously filed in the present application on March 22, 2002. An Appeal Brief was submitted on May 22, 2002, and thereafter the Examiner withdrew the finality of the rejections in the application and presented new grounds for rejection of the claims. Therefore, the Examiner never submitted a written answer to the Appeal Brief, thus dismissing the appeal from the appeal process.

III. STATUS OF CLAIMS

Claims 16, 23, 43, 49, 57 and 60 have been cancelled from the application. Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by JP 05-220225 in view of Samson, U.S. Patent No. 5,702,373. Samson is relied upon by the Examiner for description of the JP 05-220225 document. Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Leoni, U.S. Patent No. 5,772,681. Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 stand finally rejected under 35

U.S.C. §103(a) as being unpatentable over Cook, U.S. Patent No. 4,637,396, in view of Cox, U.S. Patent No. 5,257,974. Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Cook in view of Cox, and further in view of Leoni. Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni, in view of Andersen et al., U.S. Patent No. 5,674,276. Claims 17, 22, 44 and 48 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni, in view of Jang et al., U.S. Patent No. 4,898,591. Claims 17, 22, 44 and 48 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Cook and Cox, and further in view of Jang et al. Claims 51 and 52 are objected to by the Examiner as being dependent upon a rejected base claim, but the Examiner asserts these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

A Response After Final was filed on January 14, 2005 in which no claim amendments were made, but all pending claims, including updated status identifiers, were presented in a clean version along with accompanying remarks requesting reconsideration in response to a Final Office Action mailed November 16, 2004. An Advisory Action was mailed on February 2, 2005, stating the request for reconsideration was considered, but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER¹

The invention relates to catheters or, more particularly, catheter shaft sections with improved designs. The inventive catheter shaft section includes an elongate tubular member comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member. As illustrated in Figure 4, the knit tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable.

Turning now to the claims, claim 1 recites a catheter section (Figures 2 and 3, reference number 122) comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends. The elongate tubular member comprises a knit tubular member (Figures 2 and 3, reference number 128) and an inner tubular liner (Figure 3, reference number 126) in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops (Figure 4 and Specification, page 8, lines 9-10) and is generally not radially expandable (Specification, page 8, lines 17-20).

Claim 2, which depends from claim 1, further recites that the knit tubular member comprises a metal alloy (Specification, page 7, line 20).

Claim 3, which depends from claim 1, further recites that the knit tubular member comprises a superelastic alloy (Specification, page 7, lines 20-22). Claim 4, which depends from claim 3, recites that the superelastic alloy is a nickel-titanium alloy (Specification, page 7, lines 22-24). Claim 5, which depends from claim 3, recites that the superelastic alloy is nitinol (Specification, page 7, lines 22-24).

¹ The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

Claim 6, which depends from claim 1, further recites that the knit tubular member comprises stainless steel (Specification, page 7, lines 20-22).

Claim 7, which depends from claim 1, further recites that the knit tubular member comprises a platinum alloy (Specification, page 7, lines 20-22).

Claim 8, which depends from claim 1, further recites that the knit tubular member comprises a non-metallic material (Specification, page 7, line 30 through page 8, line 2). Claim 9, which depends from claim 8, recites that the non-metallic material is a polymeric material (Specification, page 7, line 30 through page 8, line 2).

Claim 10, which depends from claim 1, further recites that the knit tubular member comprises a multifilament wire (Specification, page 8, lines 13-15). Claim 11, which depends from claim 10, further recites that the multifilament wire comprises stainless steel and platinum (Specification, page 8, lines 13-16). Claim 12, which depends from claim 10, further recites that the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol (Specification, page 8, line 13-16).

Claim 13, which depends from claim 1, further recites that the knit tubular member is formed from wire having a generally circular cross-sectional shape (Specification, page 8, lines 3-5). Claim 14, which depends from claim 13, further recites that the wire has a diameter of about 0.3 mil—1.5 mil (Specification, page 8, lines 5-6, as amended in an Amendment filed September 26, 2003, of which finds 35 U.S.C. §112, First Paragraph support in claim 14 as originally filed).

Claim 15, which depends from claim 1, further recites that the knit tubular member comprises a first strand made from a first material and a second strand made from a second material (Specification, page 8, lines 11-13).

Claim 54, which depends from claim 1, recites that the catheter section further comprises an outer tubular cover (Figure 3, reference number 130) extending over the knit tubular member. Claim 17, which depends from claim 54, further recites that the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, fluoropolymers including PFTB, FEP, Nylon, polyether block amide, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers (Specification, page 6, line 29 through page 7, line 10). Claim 18, which depends from claim 54, further recites that the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member (Specification, page 6, lines 15-17). Claim 19, which depends from claim 54, further recites that the outer tubular cover is extruded onto the knit tubular member (Specification, page 6, lines 15-17). Claim 20, which depends from claim 54, further recites that the outer tubular cover is bonded onto the knit tubular member (Specification, page 6, lines 15-17). Claim 21, which depends from claim 54, further recites that at least one of the inner tubular liner and the outer tubular cover are radiopaque (Specification, page 7, lines 15-19).

Claim 22, which depends from claim 1, further recites that the inner tubular liner comprises a material selected from the group consisting of polyethylene, fluoropolymer, Nylon, polyether block amide, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyethylene terephthalate (PET), and their mixtures, alloys, and copolymers (Specification, page 6, lines 18-22).

Claim 55, which depends from claim 1, further recites that the knit tubular member is in contact with the inner tubular liner (Figure 3, reference number 126).

Claim 56, which depends from claim 1, further recites that the knit tubular member is formed from a plurality of tightly knit interlocking loops (Specification, page 8, lines 17-20).

Claim 61, which depends from claim 1, further recites that the up loops and down loops are the same size (Specification, page 8, lines 9-10).

Claim 24 is an independent claim directed to a catheter section (Figures 2 and 3, reference number 122) comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends. The elongate tubular member comprises an inner liner (Figure 3, reference number 126), an outer cover (Figure 3, reference number 130), and a knit tubular member (Figures 2 and 3, reference number 128) formed from a metal wire (Specification page 7, line 20) forming a plurality of interlocking up loops and down loops (Figure 4 and Specification, page 8, lines 9-10), wherein the knit tubular member is generally not radially expandable (Specification, page 8, lines 17-20).

Claim 25, which depends from claim 24, further recites that the metal wire comprises a superelastic alloy (Specification, page 7, lines 20-26). Claim 26, which depends from claim 25, further recites that the superelastic alloy is nitinol (Specification, page 7, lines 22-24).

Claim 27, which depends from claim 24, further recites that the metal wire has a generally circular cross-section (Specification, page 8, lines 3-5).

Claim 28, which depends from claim 24, further recites that the metal wire is a multifilament wire (Specification, page 8, lines 13-15). Claim 29, which depends from claim 28, further recites that the multifilament wire comprises stainless steel and platinum (Specification, page 8, lines 13-16). Claim 30, which depends from claim 28, further recites the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol (Specification, page 8, lines 13-16).

Claim 62, which depends from claim 24, further recites that the up loops and down loops are the same size (Specification, page 8, lines 9-10).

Claim 31 is an independent claim directed to a catheter (Figure 1, reference number 100) comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends. The elongate tubular member comprises a relatively stiff proximal segment (Figure 1, reference number 106) and a relatively flexible distal segment (Figure 1, reference number 102 and Figures 2 and 3, reference number 122) comprising a knit tubular member (Figures 2 and 3, reference number 128) and an inner tubular liner (Figure 3, reference number 126) in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops (Figure 4 and Specification, page 8, lines 9-10) and is generally not radially expandable (Specification, page 8, lines 17-20).

Claim 32, which depends from claim 31, further recites that the knit tubular member comprises a superelastic alloy (Specification, page 7, lines 20-22). Claim 33, which depends from claim 32, further recites that the superelastic alloy is nitinol (Specification, page 7, line 22-24).

Claim 34, which depends from claim 31, further recites that the knit tubular member comprises stainless steel (Specification, page 7, lines 20-22).

Claim 35, which depends from claim 31, further recites that the knit tubular member comprises a platinum alloy (Specification, page 7, lines 20-22).

Claim 36, which depends from claim 31, further recites that the knit tubular member comprises a non-metallic material (Specification, page 7, line 30 through page 8, line 2). Claim 37, which depends from claim 36, further recites that the non-metallic material is a polymeric material (Specification, page 7, line 30 through page 8, line 2).

Claim 38, which depends from claim 31, further recites that the knit tubular member comprises a multifilament wire (Specification, page 8, lines 13-15). Claim 39, which depends from claim 38, further recites that the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol (Specification, page 8, lines 13-16).

Claim 40, which depends from claim 31, further recites that the knit tubular member is formed from wire having a generally circular cross-sectional shape (Specification, page 8, lines 3-5). Claim 41, which depends from claim 40, further recites that the wire has a diameter of about 0.3 mil—1.5 mil (Specification, page 8, lines 5-6, as amended in an Amendment filed September 26, 2003, of which finds 35 U.S.C. §112, First Paragraph support in claim 41 as originally filed).

Claim 42, which depends from claim 31, further recites that the knit tubular member comprises a first strand made from a first material and a second strand made from a second material (Specification, page 8, lines 11-13).

Claim 58, which depends from claim 31, recites that the catheter further comprises an outer tubular cover (Figure 3, reference number 130) extending over the knit tubular member. Claim 44, which depends from claim 58, further recites that the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, Nylon, polyether block amide, fluoropolymers including PTFE, FEP, low density polyethylene, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers (Specification, page 6, line 29 through page 7, line 10). Claim 45, which depends from claim 58, further recites that the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member (Specification, page 6, lines 13-17 and page 6, line 29 thru page 7, line 7). Claim 46, which depends from claim 58, further

recites that the outer tubular cover is extruded onto the knit member (Specification, page 6, lines 15-17). Claim 47, which depends from claim 58, further recites that the outer tubular cover is bonded on the knit member (Specification, page 6, lines 15-17). Claim 48, which depends from claim 58, further recites that at least one of the inner tubular liner and the outer tubular cover are radiopaque (Specification, page 7, lines 15-19).

Claim 50, which depends from claim 31, further recites that the proximal segment has an inner proximal liner and an outer proximal cover (Specification, page 10, lines 1-2). Claim 51, which depends from claim 50, recites that the proximal segment further comprises a braid interposed between the inner proximal liner and the outer proximal cover (Specification, page 10, lines 1-12). Claim 52, which depends from claim 50, recites that the proximal segment further comprises a coil interposed between the inner proximal liner and the outer proximal cover (Specification, page 10, lines 1-12).

Claim 53, which depends from claim 31, further recites that the knit tubular member extends into the proximal segment (Specification, page 10, lines 8-9).

Claim 59, which depends from claim 31, further recites that the knit tubular member is formed from a plurality of tightly knit interlocking loops (Specification, page 8, lines 17-20).

Claim 63, which depends from claim 31, further recites that the up loops and the down loops are the same size (Specification, page 8, lines 9-10).

VI GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. *Whether claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 are unpatentable under 35 U.S.C. §102(b) as being anticipated by JP 05-220225, in view of Samson, U.S. Patent No. 5,702,373, relied upon by the Examiner for description of the JP 05-220225 document.*
2. *Whether claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 are unpatentable under 35 U.S.C. §102(e) as being anticipated by Leoni, U.S. Patent No. 5,772,681.*
3. *Whether claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 are unpatentable under 35 U.S.C. §103(a) over Cook, U.S. Patent No. 4,637,396, in view of Cox, U.S. Patent No. 5,257,974.*
4. *Whether claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are unpatentable under 35 U.S.C. §103(a) over Cook, U.S. Patent No. 4,637,396, in view of Cox, U.S. Patent No. 5,257,974, and further in view of Leoni, U.S. Patent No. 5,772,681.*
5. *Whether claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 are unpatentable under 35 U.S.C. §103(a) over JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, in view of Andersen et al., U.S. Patent No. 5,674,276.*
6. *Whether claims 17, 22, 44 and 48 are unpatentable under 35 U.S.C. §103(a) over JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, in view of Jang et al., U.S. Patent No. 4,898,591.*
7. *Whether claims 17, 22, 44 and 48 are unpatentable under 35 U.S.C. §103(a) over Cook, U.S. Patent No. 4,637,396, and Cox, U.S. Patent No. 5,257,974, and further in view of Jang et al., U.S. Patent No. 4,898,591.*

VII. ARGUMENT

A. *Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 are patentable over the §102(b) rejection relying on JP 05-220225 supplemented by the Examiner's reliance of Samson, U.S. Patent No. 5,702,373, for description of the JP 05-220225 document.*

1. *The Examiner improperly relies on the JP 05-220225 document.*

The Examiner suggests JP 05-220225 anticipates the stated rejected claims of the present invention. In upholding the rejection, the Examiner appears to be solely relying on a single paragraph in Samson which briefly characterizes the Japanese document as teaching a "wire layer which is tightly knitted at the proximal section of the catheter and more loosely knitted at a midsection." See Samson, Column 4, Lines 35-41. The Examiner has made a machine-assisted English translation of JP 05-220225 prepared by Thomson Derwent available in the file and accessible on Private PAIR.² Additionally, the Applicants have previously provided a computer translation of JP 05-220225 available from the Japanese Patent Office website (www.jpo.go.jp) with an Amendment mailed May 10, 2004.³ A cursory inspection of these documents shows a disparity of the teachings of the underlying Japanese document. In view of this inconsistency, the Applicants suggest reliance on a machine translation is inappropriate. M.P.E.P. §706.02 states that "[i]f the [prior art] document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection." No certified English translation has been provided as to date, and thus the precise disclosure of the Japanese document has not been established. In *Ex parte Jones*, the Board of Patent Appeals and Interferences expressed its discouragement of the use of foreign language documents in

² A copy is provided in the Documents Appendix.

³ A copy is provided in the Documents Appendix.

rejections and the Examiner's apparent burden of providing translations of such documents when necessary. See *Ex parte Jones*, 62 USPQ2d 1206 (Bd. Pat. App. & Inter. 2001) (unpublished). Therefore, the Examiner's reliance on the JP 05-220225 document as disclosing claimed limitations of the currently claimed invention that the Japanese document does not fairly disclose is without merit.

2. *JP 05-220225 fails to teach or suggest each and every element and structural limitation of the claimed invention.*

"For anticipation under 35 U.S.C. §102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02. Claims 1, 24 and 31 each teach, *inter alia*, a knit tubular member formed from a plurality of interlocking up loops and down loops, wherein the knit tubular member is generally not radially expandable. JP 05-220225 at least fails to teach a knit tubular member, including all the structural limitations, as currently claimed. Therefore, an anticipatory rejection is improper. Although the English language translation of JP 05-220225 uses the term "knitted," it is clear that JP 05-220225 fails to teach a knitted member with all the structural limitations as claimed in the current application. It appears as if the Examiner is relying on JP 05-220225 as teaching a knit member, while disregarding the remainder of the elements claimed in the present invention. For example, the Examiner has failed to identify where JP 05-220225 teaches a knit member formed from a plurality of interlocking up loops and down loops or a knit member generally not radially expandable.

Independent claims 1, 24 and 31 recite a knit tubular member formed from a plurality of interlocking up and down loops that is generally not radially expandable. JP 05-220225 fails to teach either of these structural limitations of the claimed invention. The figures of JP 05-

220225, especially Figures 5A and 7A, show the wires in a woven or crisscross pattern. The figures clearly do not show interlocking up and down loops, as is recited in the instant claims. The figures in JP 05-220225 show a woven or braided member wherein the wires are wrapped in a helical fashion, whereby there are no interlocking up and down loops present. Thus, when the figures of the Japanese document are viewed in light of the accompanying description, it is clear that the term "knit" as used in the document is a surrogate for meaning that the wire is actually woven or braided. There is no teaching or suggestion in the Japanese document of a knit tubular member formed from a plurality of interlocking up and down loops as is instantly claimed.

Likewise, at no point has the Examiner identified where JP 05-220225 teaches a knit member which is generally not radially expandable. This structural limitation must be taught by the prior art reference in order to anticipate the current claims. Applicants' request that the Examiner identify the location where the Japanese document teaches this structural limitation has gone unanswered. The Examiner simply asserted in the Final Office Action mailed November 16, 2004, "[t]he dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention." To the contrary, one of skill in the art, upon reviewing the English translation and figures of the Japanese document, would likely conclude that the reinforcing layer (35) was radially expandable in order to achieve the transition from the area of tightly woven wires (35A) to loosely woven wires (35B). See JP 05-220225, paragraph 18. The Examiner has not indicated what language or which figures in JP 05-220225 is being relied on for a teaching of the knit member not being radially expandable.

3. *The definition given to the term "knitted" as used in the current application is dissimilar to that used in JP 05-220225.*

Although the English translation of JP 05-220225 uses the term "knitted" in describing a

reinforcement layer, a reference must be considered for all that it fairly teaches. The Examiner states that the reference must be read in light of its plain meaning. However, Applicants assert the word "knitted" must be construed in view of the specification and the accompanying drawings and must not be given a definition contrary to that disclosed in the document. The Examiner appears to rely solely on the word "knitted" used in the English translation of JP 05-220225 without further evaluation of the document. The Examiner asserted in the Final Office Action mailed November 16, 2004, "[t]he dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention," while rejecting any reliance on the drawings as "a tortuous exercise that is inconclusive and clearly misleading" since the "sketchy figures...lack the appropriate details to accurately discern the elemental structure." Applicants disagree with the Examiner's reliance on the word "knitted" without construing the term in view of the specification and the accompanying drawings. A reference cannot anticipate a claim "by possessing identically named parts," unless those parts also "have the same structure or otherwise satisfy the claim limitations, and were understood to function in the same way by one skilled in the art." *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed. Cir. 1998). The layer taught in JP 05-220225 and shown in Figures 4-7 does not have the same structure as the knitted member of the currently claimed invention; therefore, the reference fails to anticipate the current claims. The Examiner's sole reliance on the word "knit" and failure to recognize the structural differences shown in the drawings in upholding the rejection are without merit.

The machine translation obtained by the Applicants from the Japanese Patent Office website and provided to the Examiner with a Response dated May 10, 2004, suggests a dissimilar definition of "knitted" than that intended in the present application. In the detailed

description of the translation, the method of manufacturing the catheter is described as including forming the wire layer by turns. See JP 05-220225, paragraphs 19 and 23. This description follows what is shown in the figures, which is a wire net that is woven or braided. Additionally, there is a reference to the different pitches in the tight and loose sections. See JP 05-220225, paragraph 19. It is well known in the art that the term "pitch" is commonly used to denote the angle of the strands in a woven or braided material. Thus, when the figures of JP 05-220225 are viewed in light of the specification, it is clear that the term "knit" is being used in a manner dissimilar to that intended in the present application.

There are at least three plain meanings of "knit," provided in the Merriam-Webster Online Dictionary⁴ (obtainable at www.m-w.com), including (1) to tie together; (2) to link firmly or closely; and (3) to form by interlacing yarn or thread in a series of connected loops with needles. Given the different plain meanings possible for "knit," the skilled artisan would logically turn to the figures in the Japanese document in an attempt to determine which meaning of "knit" was intended by the reference. The figures, especially Figures 5A and 7A, show the wires in a woven or crisscross pattern. The figures in JP 05-220225 clearly do not show interlocking up and down loops, as is recited in the currently claimed invention.

The Examiner appears to be selecting a definition of "knit" that is contrary to the figures in the reference in order to assert the reference teaches the claimed invention. Without using the instant specification for guidance, the skilled artisan would interpret the "knitted" reinforcing layer of JP 05-220225 as a woven or braided pattern, as is clearly shown in the reference's figures. While the English translation of the Japanese document uses the word "knitted," there is no teaching or suggestion in the document that the reinforcing layer is formed from a plurality of interlocking up and down loops, as is recited in the current claims.

⁴ A copy is provided in the Evidence Appendix.

4. *The Examiner's inherency argument is flawed.*

The Examiner's assertions in the Final Office Action mailed November 16, 2004, stating, "the dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention" and "the knitted nature of the member would inherently make the member generally not radially expandable" are without merit. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic." M.P.E.P. §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). As previously asserted, the term "knitted" has multiple definitions. The Merriam-Webster Online Dictionary⁵ (obtainable at www.m-w.com) states "knit" may mean: (1) to tie together; (2) to link firmly or closely; or (3) to form by interlacing yarn or thread in a series of connected loops with needles. The fact that the term "knit" has multiple meanings in view of the Figures of the JP 05-220225 reference, which clearly do not show a member formed from a plurality of interlocking up loops and down loops, rebuts any attempt by the Examiner to claim the limitations are inherently present in the prior art reference. Furthermore, adopting the Examiner's assertion in the Final Office Action mailed November 16, 2004, without conceding the correctness of the statement, that "the figures lack the appropriate details to accurately discern the elemental structure," it is improper for the Examiner to make a definitive assertion that JP 05-220225 discloses a knit member formed from a plurality of interlocking up loops and down loops if "knit" can have multiple definitions and the Examiner fails to construe the term in view of the specification and/or drawings.

⁵ A copy is provided in the Evidence Appendix.

Additionally, a knitted member, such as the knitted middle layer 23 taught in Cook, U.S. Patent No. 4,637,396, may be expandable. Therefore, a knitted member is not necessarily not radially expandable as the Examiner erroneously concludes in asserting the structural limitation is inherent in the prior art. Because these limitations are not necessarily taught by the JP 05-220225 reference, the inherency argument suggested by the Examiner is without merit, and JP 05-220225 fails to teach each and every element of the claimed invention. In light thereof, reversal of the rejection based on JP 05-220225 is requested.

B. *Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 are patentable over the §102(e) rejection relying on Leoni, U.S. Patent No. 5,772,681.*

1. *Leoni fails to teach or suggest each and every element and structural limitation of the claimed invention.*

Leoni teaches a dilation catheter having an expandable balloon section (11). The balloon section (11) has a reinforcement net (2) made of metallic monofilaments extending helically around the longitudinal axis of the balloon section (11) and moveable with respect to each other at the crossover points (5) to allow expansion of the balloon section (11). See Leoni, Abstract. The reinforcement net (2) may be wound, braided or knitted. See Leoni, column 2, lines 58-60.

Although Leoni seems to teach a reinforcing net comprising metallic monofilaments that may be helically wound, braided or knitted, Leoni's teachings must be read in light of the specification. Identically named parts in a prior art reference must have the same structure or otherwise satisfy the claim limitations in order to anticipate. See *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed. Cir. 1998).

As discussed above regarding the teachings of JP 05-220225, the Merriam-Webster

Online Dictionary (obtainable at www.m-w.com) contains multiple definitions for the word "knit." Given the different plain meanings possible for "knit," the skilled artisan would logically turn to the remainder of the specification and accompanying figures in the reference in an attempt to determine which meaning of "knit" was intended by the reference. It is apparent from a close examination of Leoni that the definition of "knitted" relied on in Leoni is dissimilar to that intended in the current application. Leoni teaches a reinforcing net made of metallic monofilaments wherein the contact points of the mesh rows are moveable with respect to each other in the crossover points. See Leoni, column 3, lines 55-60. The limitation that the reinforcing net includes mesh rows extending helically around the longitudinal axis, wherein the mesh rows are moveable with respect to each other in the crossover points is as equally limiting for a knitted reinforcing net as it is for a braided reinforcing net as taught in Leoni. See Leoni, column 6, lines 16-34. Claim 6 of Leoni states in part, "wherein said reinforcement net (2) is a knitted net of metallic monofilaments, mesh rows of said net extending helically around the longitudinal axis of the middle section...wherein said mesh rows are moveable with respect to each other in the crossover points (5) during expansion of the balloon section." Thus, the reinforcement net disclosed in Leoni does not have the same structure or otherwise satisfy the structural claim limitations of the current claims. The crossover points are not points of interlocking loops as currently claimed, but are points wherein the mesh rows are moveable with respect to each other. It follows that the definition of "knit" relied on by Leoni is dissimilar from the definition intended in the current application. Further, the structure of the reinforcing mesh is made of metallic monofilaments extending helically around the longitudinal axis of the balloon section and moveable with respect to each other at the crossover points to allow expansion of the balloon section. Therefore, it is apparent that Leoni fails to teach a knitted

tubular member formed from a plurality of interlocking up loops and down loops that is generally not radially expandable.

2. *The Examiner's inherency argument is flawed.*

The Examiner asserted in the Final Office Action mailed November 16, 2004, that "[t]he up and down loops of the knitted member is inherent in view of the dictionary definition of knitted." As stated above regarding the Examiner's inherency argument with respect to the teachings of JP 05-220225, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). It is clear that the missing descriptive matter (i.e., the interlocking up and down loops of the knitted member) is not necessarily present in the reinforcement mesh described in Leoni. The multiple dictionary definitions for knit as well as the description and accompanying drawings describing the reinforcement net of Leoni demonstrate that not only is the claimed limitation not necessarily present in the reference, but Leoni actually teaches a knit member having a dissimilar structure (i.e., the mesh rows of the knitted net are moveable with respect to each other at the crossover points) from the one currently claimed. Therefore, the inherency argument relied on by the Examiner lacks merit, and Leoni fails to anticipate the claimed invention. In light thereof, reversal of the rejection based on Leoni is requested.

C. *Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, and Cox, U.S. Patent No. 5,257,974.*

1. *A reference used to establish a prima facie case of obviousness must be*

analogous art.

In relying on a reference under 35 U.S.C. §103(a), the reference must either be in the field of the Applicant's invention or be reasonably pertinent to the particular problem in which the inventor is concerned. M.P.E.P. §2141.01(a). "While Patent Office classification of references and the cross-references in the official search notes are some evidence of 'nonanalogy' or 'analogy' respectively, the court has found 'the similarities and differences in structure and function of the inventions to carry far greater weight.'" *In re Ellis*, 476, F.2d 1370, 1372, cited at M.P.E.P. §2141.01(a). Neither the art taught in Cook, nor the art taught in Cox are analogous to that of the currently claimed invention or to one another. Furthermore, the knitted member of the current invention functions much differently from that taught in Cook. The knit member in Cook is designed of elastic filaments to provide expansion and contraction characteristics of the balloon. See Cook, column 3, lines 46-48. However, the knit member of the currently claimed invention provides kink resistance and flexibility to a catheter shaft. See Specification, page 3, lines 18-29. Therefore, the inventions taught by Cook and Cox are nonanalogous to that of the currently claimed invention.

2. *There is no suggestion or motivation to combine the teachings of Cook with the teachings of Cox.*

The three basic criteria necessary to establish a *prima facie* case of obviousness with the cited combination are not met with the cited combination of references. Namely, the cited combination at least lacks any suggestion or motivation to combine the teachings of Cook with the teachings of Cox. See M.P.E.P. §2143.01. The teaching or suggestion to make the claimed combination must be found in the prior art, and not in the Applicant's own disclosure. See M.P.E.P. §2143.

i. *The references teach away from one another.*

In ascertaining the differences between the prior art and the currently claimed invention, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. §2141.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) (emphasis in original). The teachings of Cook and Cox actually teach away from one another. Cox teaches an adapter for use with balloons of intravascular balloon catheters. The adapter of Cox may include a support structure comprising reinforcing fibers woven in the shape of a tube. See Cox, column 8, lines 31-34. Cook teaches that an expandable balloon having a knitted layer is superior to prior known fabric reinforced balloons because,

Prior known balloons reinforced with a braided or woven fabric tube are unable to expand in diameter without correspondingly decreasing in length. However, a balloon reinforced with the knitted fabric tube described herein is capable of expanding three-dimensionally such that an increase in diameter does not require a decrease in length of the balloon.

Cook, column 3, lines 48-55 (emphasis added). Therefore, Cook actually teaches away from the teachings of Cox. The language of Cook cited above would discourage one from substituting a woven or braided member for the knitted member of Cook. Additionally, Cox teaches adding a support structure to enhance the radial rigidity of the adapter. However, the knitted layer of Cook is capable of expanding three-dimensionally; therefore, such a knitted layer taught in Cook would not provide the desired radial rigidity which the added support structure of Cox is intended to provide. Therefore, in view of the express teachings of the references, there is no motivation or suggestion to combine the teachings of Cook with those of Cox, and the references actually teach away from one another. Thus, no *prima facie* case of obviousness has been established with the cited combination.

ii. *Modification of one reference with the teachings of the other reference would render the modified apparatus unsatisfactory for its intended purpose.*

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation for combining the teachings of the references found in the prior art. M.P.E.P. §706.02(j). "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. §2143.01, quoting *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). It is apparent that any modification of Cox or Cook with the teachings of the other would make the modified prior art invention unsatisfactory for its intended purpose; therefore, there is no motivation or suggestion to combine the teachings of Cook with the teachings of Cox required to establish *prima facie* obviousness.

Cook teaches a balloon catheter having a balloon reinforced by a knitted layer comprising elastic and inelastic plies. See Cook, column 3, lines 10-15. The knitted middle layer (23), as shown in Figure 2, is an interior layer of the balloon positioned between the inner layer (22) and the outer layer (24). By using elastic plies, the knitted layer is expandable, and the knitted layer is chosen for its expansion and contraction characteristics. See Cook, column 3, lines 45-48. Therefore, the expandable knitted layer imbedded in the balloon allows the balloon to expand to a predetermined diameter.

Cox, on the other hand, teaches an adapter for use with balloons of intravascular balloon catheters. The adapter, which may be placed about the exterior of the balloon, is preferably made of a material providing radial rigidity to the adapter, and serves to restrict the balloon's radial size. See Cox, column 5, lines 41-44. The adapter of Cox may include a support structure comprising reinforcing fibers woven in the shape of a tube. See Cox, column 8, lines 31-34.

The woven support structure is included in order to enhance the radial rigidity of the adapter. See Cox, column 8, lines 44-45. It is clear that any support structure added to the adapter of Cox is intended to provide enhanced rigidity to the adapter to reduce radial expansion.

Modifying the Cook reference with the woven support structure suggested in Cox would impart undesired rigidity into the balloon of Cook and prevent desired expansion of the balloon, therefore making the modified invention unsatisfactory for its intended purpose. Likewise, modifying Cox with the expandable knitted member taught in Cook would impart undesired expansion to the adapter taught in Cox. The expandable knitted member would not aid in enhancing the radial rigidity of the adapter; therefore, the proposed modification would not improve the performance of the adapter taught in Cox. Because such a proposed modification of either reference would render the prior art invention unsatisfactory for its intended purpose, there is no motivation to combine the teachings of Cox and Cook. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

D. *Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, Cox, U.S. Patent No. 5,257,974, and Leoni, U.S. Patent No. 5,772,681.*

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the remarks provided above concerning each of the references are equally applicable to the instantly cited combination. The references at least fail to teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable.

Additionally, there is no motivation to combine the teachings of the combination of references in order to reach the invention as claimed in the rejected claims. As stated above, there is no motivation or suggestion to combine the teachings of Cook with those of Cox. The references actually teach away from one another and modification of one in view of the other would make the modified device unsatisfactory for its intended purpose. Leoni fails to provide motivation to combine the references lacking in Cook and Cox. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

E. *Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, and Andersen et al., U.S. Patent No. 5,674,276.*

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the cited combination at least fails to teach each and every element of the claimed invention. As explained above, neither JP 05-220225 nor Leoni teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable. Andersen et al., relied on by the Examiner to teach using multifilaments with first and second materials of a metal and a polymer, fail to remedy the shortcomings of JP 05-220225 and Leoni. Andersen et al. teach a tubular stent graft formed of loosely interlocked knitted loops. See Andersen et al., column 4, lines 25-27. However, the tubular stent graft is self-expanding or otherwise readily expandable. See Andersen, column 3, lines 18-20. Therefore, Andersen et al. at least fail to teach a knitted member that is generally not radially expandable.

Additionally, there is no motivation to combine the teachings of Andersen et al. with those of either JP 05-220225 or Leoni. The stent graft taught in Andersen et al. is nonanalogous to the catheter shaft taught in either JP 05-220225 or the dilation balloon taught in Leoni. Furthermore, the nature of the problem to be solved in Andersen et al. is dissimilar to that of either JP 05-220225 or Leoni. One of skill in the art would not be inclined to look to an expandable stent graft as taught in Andersen et al. in an attempt to modify the device taught in either JP 05-220225 or Leoni. There is no motivation, either expressly or impliedly, to make the suggested combination. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

F. *Claims 17, 22, 44 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on JP 05-220225 or Leoni, U.S. Patent No. 5,772,681, and Jang et al., U.S. Patent No. 4,898,591.*

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the cited combination at least fails to teach each and every element of the claimed invention. As explained above, neither JP 05-220225 nor Leoni teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable. Jang et al., relied on by the Examiner to teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, fail to remedy the shortcomings of JP 05-220225 and Leoni. Jang et al. suggest a braided body portion, but fail to teach a knitted tubular member including all relevant structural limitations as currently claimed. As stated above, the dissimilar characteristics of a braided member and a knitted member as

currently claimed are not insignificant. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the combination is requested.

G. Claims 17, 22, 44 and 48 are patentable over the 35 U.S.C. §103(a) rejection relying on Cook, U.S. Patent No. 4,637,396, Cox, U.S. Patent No. 5,257,974, and Jang et al., U.S. Patent No. 4,898,591.

The three requirements of establishing a *prima facie* case of obviousness have not been met with the cited combination. Namely, the cited combination at least fails to teach each and every element of the claimed invention. As explained above, neither Cook nor Cox individually or in combination teach a knit tubular member formed from a plurality of interlocking up loops and down loops and that is generally not radially expandable. Jang et al., relied on by the Examiner to teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, fail to remedy the shortcomings of Cook and Cox. Jang et al. suggest a braided body portion, but fail to teach a knitted tubular member including all relevant structural limitations as currently claimed. As stated above, the dissimilar characteristics of a braided member and a knitted member as currently claimed are not insignificant.

Additionally, as stated above, there is no motivation to combine the teachings of Cook with those of Cox. The references actually teach away from one another and modification of one in view of the other would make the modified device unsatisfactory for its intended purpose. Jang et al. fail to remedy the shortcomings of Cook and Cox and provide motivation to combine the teachings of the cited combination. In light thereof, a *prima facie* case of obviousness has not been established with the combination, and reversal of the rejection based on the

combination is requested.

H. Conclusion.

For the reasons stated above, the rejection of claims 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 under 35 U.S.C. §§102(b), 102(e) and 103(a) should be reversed.

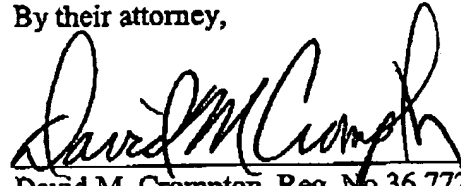
Respectfully submitted,

Jill McFadden, et al.

By their attorney,

Date: _____

9/15/06



David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

RECEIVED
CENTRAL FAX CENTER

SEP 15 2006

VIII. CLAIMS APPENDIX

1. A catheter section comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends, said elongate tubular member comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable.
2. The catheter section of claim 1 wherein the knit tubular member comprises a metal alloy.
3. The catheter section of claim 1 wherein the knit tubular member comprises a superelastic alloy.
4. The catheter section of claim 3 wherein the superelastic alloy is a nickel-titanium alloy.
5. The catheter section of claim 3 wherein the superelastic alloy is nitinol.
6. The catheter section of claim 1 wherein the knit tubular member comprises stainless steel.
7. The catheter section of claim 1 wherein the knit tubular member comprises a platinum alloy.
8. The catheter section of claim 1 wherein the knit tubular member comprises a non-metallic material.
9. The catheter section of claim 8 wherein the non-metallic material is a polymeric material.

10. The catheter section of claim 1 wherein the knit tubular member comprises a multifilament wire.

11. The catheter section of claim 10 wherein the multifilament wire comprises stainless steel and platinum.

12. The catheter section of claim 10 wherein the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol.

13. The catheter section of claim 1 wherein the knit tubular member is formed from wire having a generally circular cross-sectional shape.

14. The catheter section of claim 13 wherein the wire has a diameter of about 0.3 mil – 1.5 mil.

15. The catheter section of claim 1 wherein the knit tubular member comprises a first strand made from a first material and a second strand made from a second material.

17. The catheter section of claim 54 wherein the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, fluoropolymers including PTFE, FEP, Nylon, polyether block amide, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers.

18. The catheter section of claim 54 wherein the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member.

19. The catheter section of claim 54 wherein the outer tubular cover is extruded onto the knit tubular member.

20. The catheter section of claim 54 wherein the outer tubular cover is bonded onto the knit tubular member.

21. The catheter section of claim 54 wherein at least one of the inner tubular liner and the outer tubular cover are radiopaque.

22. The catheter section of claim 1 wherein the inner tubular liner comprises a material selected from the group consisting of polyethylene, fluoropolymer, Nylon, polyether block amide, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyethylene terephthalate (PET), and their mixtures, alloys, and copolymers.

24. A catheter section comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between the proximal and distal ends, said elongate tubular member comprising an inner liner, an outer cover, and a knit tubular member formed from a metal wire forming a plurality of interlocking up loops and down loops, wherein the knit tubular member is generally not radially expandable.

25. The catheter section of claim 24 wherein the metal wire comprises a superelastic alloy.

26. The catheter section of claim 25 wherein the superelastic alloy is nitinol.

27. The catheter section of claim 24 wherein the metal wire has a generally circular cross-section.

28. The catheter section of claim 24 wherein the metal wire is a multifilament wire.

29. The catheter section of claim 28 wherein the multifilament wire comprises stainless steel and platinum.

30. The catheter section of claim 28 wherein the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol.

31. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:

a relatively stiff proximal segment; and

a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable.

32. The catheter of claim 31 wherein the knit tubular member comprises a superelastic alloy.

33. The catheter of claim 32 wherein the superelastic alloy is nitinol.

34. The catheter of claim 31 wherein the knit tubular member comprises stainless steel.

35. The catheter of claim 31 wherein the knit tubular member comprises a platinum alloy.

36. The catheter of claim 31 wherein the knit tubular member comprises a non-metallic material.

37. The catheter of claim 36 wherein the non-metallic material is a polymeric material.

38. The catheter of claim 31 wherein the knit tubular member comprises a multifilament wire.

39. The catheter of claim 38 wherein the multifilament wire comprises material selected from the group consisting of stainless steel, platinum, and nitinol.

40. The catheter of claim 31 wherein the knit tubular member is formed from wire having a generally circular cross-sectional shape.

41. The catheter of claim 40 wherein the wire has a diameter of about 0.3 mil. – 1.5 mil.

42. The catheter of claim 31 wherein the knit tubular member comprises a first strand made from a first material and a second strand made from a second material.

44. The catheter of claim 58 wherein the outer tubular cover comprises a material selected from the group consisting of polyimide, polyamide, polyethylene, polypropylene, polyvinylchloride, Nylon, polyether block amide, fluoropolymers including PTFE, FEP, low density polyethylene, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers.

45. The catheter of claim 58 wherein the outer tubular cover comprises a polymer which can be heat-shrunk onto the knit tubular member.

46. The catheter of claim 58 wherein the outer tubular cover is extruded onto the knit member.

47. The catheter of claim 58 wherein the outer tubular cover is bonded on the knit member.

48. The catheter of claim 58 wherein at least one of the inner tubular liner and the outer tubular cover are radiopaque.

50. The catheter of claim 31 wherein the proximal segment has an inner proximal liner and an outer proximal cover.

51. The catheter of claim 50 wherein the proximal segment further comprises a braid interposed between the inner proximal liner and the outer proximal cover.

52. The catheter of claim 50 wherein the proximal segment further comprises a coil interposed between the inner proximal liner and the outer proximal cover.

53. The catheter of claim 31 wherein the knit tubular member extends into the proximal segment.

54. The catheter of claim 1 further comprising an outer tubular cover extending over the knit tubular member.

55. The catheter of claim 1 wherein the knit tubular member is in contact with the inner tubular liner.

56. The catheter of claim 1 wherein the knit tubular member is formed from a plurality of tightly knit interlocking loops.

58. The catheter of claim 31 further comprising an outer tubular cover extending over the knit tubular member.

59. The catheter of claim 31 wherein the knit tubular member is formed from a plurality of tightly knit interlocking loops.

61. The catheter of claim 1 wherein the up loops and down loops are the same size.

62. The catheter of claim 24 wherein the up loops and down loops are the same size.

63. The catheter of claim 31 wherein the up loops and down loops are the same size.

IX. EVIDENCE APPENDIX

A. Merriam-Webster Online Dictionary (www.m-w.com) submitted with Amendment dated May 10, 2004. The Examiner entered the evidence as indicated in the Office Action mailed May 28, 2004 stated at page 2, paragraph 1 "Applicant's submission filed on 5/10/04 has been entered."

B. JP 05-220225 and Machine-assisted English translation of JP 05-220225 prepared by Thomson Derwent and available on Private PAIR. The Examiner entered the untranslated evidence in the Office Action mailed June 27, 2003. The Examiner entered the translated evidence in the Final Office Action mailed November 16, 2004.

C. Computer-assisted English translation of JP 05-220225 available at the Japan Patent Office website (www.jpo.go.jp) and submitted with Amendment dated May 10, 2004. The Examiner entered the evidence as indicated in the Office Action mailed May 28, 2004 stated at page 2, paragraph 1 "Applicant's submission filed on 5/10/04 has been entered."

X. RELATED PROCEEDINGS APPENDIX

There are no related appeals or interferences.

Merriam-Webster Online Dictionary

9 entries found for **knit**.

To select an entry, click on it.

knit(1,verb)	▲	Go
knit(2,noun)		
close-knit		
double knit		
knit stitch		
tight-knit	▼	

Main Entry: **'knit** ⚡

Pronunciation: 'nit

Function: *verb*Inflected Form(s): **knit** or **knit·ted**; **knit·ting**Etymology: Middle English *knitten*, from Old English *cnyttan*; akin to Old English *cnotta* knot*transitive senses*1 *chiefly dialect* : to tie together2 **a** : to link firmly or closely <*knitted* my hands> **b** : to cause to grow together <time and rest will *knit* a fractured bone> **c** : to contract into wrinkles <*knitted* her brow>

3 : to form by interlacing yarn or thread in a series of connected loops with needles

intransitive senses

1 : to make knitted fabrics or objects

2 **a** : to become compact **b** : to grow together **c** : to become drawn together- **knit·ter** *noun*

Appendix A

**This Page Is Inserted by IFW Operations
and is not a part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

Appendix B

(19)日本国特許庁(JP)

(12)公開特許公報(A)

(11)特許出願公開番号

特開平5-220225

(43)公開日 平成5年(1993)8月31日

(51)Int. Cl.

A61M 25/00

線路記号

庁内整理番号

FI

技術表示箇所

306 B 7831-4C

Z 7831-4C

審査請求 有 発明の数3(全5頁)

(21)出願番号 特願平3-236940

(22)出願日 平成3年(1991)8月26日

(71)出願人 000109543

テルモ株式会社

東京都渋谷区幡ヶ谷2丁目44番1号

(72)発明者 鈴木 龍夫

神奈川県横浜市緑区曙が丘6丁目1番地1

-12-105

(72)発明者 松本 雄

東京都調布市若葉町1丁目18番地

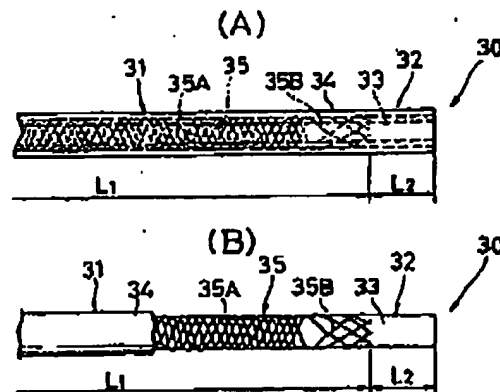
(74)代理人 弁理士 堀川 修治

(54)【発明の名称】 カテーテル

(57)【要約】

【目的】 本体部と先端部のねじり剛性の変化を緩やかなものとして、本体部の回転に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がりを防止することができるカテーテルを提供すること。

【構成】 基端から先端に至る内管部33と該内管部33を被覆する外管部34からなるカテーテル30であって、該カテーテル30は先端部32と本体部31を有し、該本体部31における内管部33と外管部34との間に一層からなる補強層35を介装し、かつ該先端部32は上記補強層35を有さず、更に前記補強層35は、本体部31における基端側の密に編まれたワイヤ層35Aと、本体部31における先端側の粗に編まれたワイヤ層35Bとからなるようにしたものである。



Appendix B

(2)

特開平5-220225

1

【特許請求の範囲】

【請求項1】 基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の密に編まれたワイヤ層と、本体部における先端側の粗に編まれたワイヤ層とからなることを特徴とするカテーテル。

【請求項2】 基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の粗に編まれたワイヤ層と、本体部における先端側の編まれないワイヤ層とからなることを特徴とするカテーテル。

【請求項3】 基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層の先端側の端部は、内管部に固定されていることを特徴とするカテーテル。

【発明の詳細な説明】

【0001】

【産業上の利用分野】本発明はカテーテルに関する。

【0002】

【従来の技術】図1に示すようなカテーテル1は、例えばガイドワイヤ等に導かれて、血管等体腔内に挿入され、その先端の方向を制御されつつ目的の部位に到達可能とされている。

【0003】そこで、このカテーテル1には、本体部2の基部をねじってその先端部3を方向づけることが可能のように、大なるねじり剛性を有することが要求される。また、先端部3に目的部位に挿入容易な形状を容易に与えることが可能であり、挿入時の先端部3が血管等の挿入経路変化に沿って容易に変形して血管等の内壁に損傷を与えないように、先端部3に柔軟性が要求される。

【0004】図2は、先端部に柔軟性を有し、かつ大なるねじり剛性を有してなる従来のカテーテル4を示す一部断面図である。カテーテル4は、可塑性の内管部5と、可塑性の外管部6との間にワイヤ層7を介装することによってねじり剛性の大きな本体部8を形成している。更に、このカテーテル4は、上記本体部8の外管部6を一部除去した端部に比較的柔軟な先端部9を接続されている。

【0005】図3は、先端部に柔軟性を有し、かつ大なるねじり剛性を有してなる従来の他のカテーテル10を

2

示す一部断面図である。このカテーテル10は、可塑性の内管部11の基端から先端手前まで第1ワイヤ層12を形成され、その先端手前から折り返して再び基端まで第2ワイヤ層13を形成された後、内管部11および両ワイヤ層12、13の上面に可塑性外管部14を被覆されている。

【0006】

【発明が解決しようとする課題】然しながら、上記カテーテル4にあっては、本体部8と先端部9との接続部に段差を生じ、血管等への挿入を円滑に行なうことが困難であり、血栓を生ずる虞れがある。また、本体部8と先端部9との接続不良により、両者間で摩擦を生ずる虞れがある。

【0007】また、上記カテーテル10は、本体部を構成する内管部11と外管部14との間に、二層の第1ワイヤ層12および第2ワイヤ層13からなる補強層が介装されていることから、補強層の厚みが大となり、カテーテルが挿入される血管等の挿入路内径により定まる所定のカテーテル外径下で、カテーテル内径が小となる。また、上記補強層の厚みが大であることから、本体部のカテーテル外径と先端部のカテーテル外径との間に比較的大なる段差を生じ、血管等への挿入を行なうことが困難となる。また、上記カテーテル10は、本体部を構成する内管部11の上面で、第1ワイヤ層12および第2ワイヤ層13を折り返すことによって形成しているもので、その全体を連続して形成し、カテーテル用基材を得ることができない。

【0008】また、カテーテルにあっては、血管体腔内への挿入作業性を向上するために、本体部と先端部のねじり剛性の変化を緩やかなものをして、本体部の回動に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がりを防止可能とすることが望まれる。

【0009】本発明は、本体部と先端部が一体形成され、ねじり剛性が大きくかつ先端部に柔軟性を有し、本体部と先端部で外径が略均一化されるとともに、比較的大なる内径を形成することができ、更に、本体部と先端部のねじり剛性の変化を緩やかなものとして、本体部の回動に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がりを防止することができ、カテーテルを提供することを目的とする。

【0010】

【課題を解決するための手段】請求項1に記載の本発明は、基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の密に編まれたワイヤ層と、本体部における先端側の粗に編まれたワイヤ層とからなるようにしたもので

Appendix B

特開平5-220225

(3)

3

ある。

【0011】請求項2に記載の本発明は、基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の編まれたワイヤ層と、本体部における先端側の編まれないワイヤ層とからなるようにしたものである。

【0012】請求項3に記載の本発明は、基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層の先端側の端部は、内管部に固定されているようにしたものである。尚、ここで言う「固定」は、補強層の先端側の端部を内管部に接着剤により接着するほか、熱をかけて内管に融着、更には補強層であるワイヤ層を内管に埋設することも含めるものとする。

【0013】

【作用】本発明によれば、下記①～④の作用効果がある。

①カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有していないようにしたので、本体部と先端部が一体形成され、ねじり剛性が大きくかつ先端部に柔軟性を有し、本体部と先端部で外径が均一化されるとともに比較的大なる内径を形成することが可能となる。

【0014】②補強層を密と粗の2段階、或いは編まれたものと編まれないものと2段階にて構成するようにしたので、本体部と先端部のねじり剛性の変化を緩やかなものとして本体部の回転に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がりを防止することが可能となる。

【0015】③補強層の先端側の端部が、内管部に固定されてなるものとするにより、製造段階における補強層端部の内管部からの剥離を防止することが可能となる。

【0016】

【実施例】図4(A)は本発明の第1実施例に係るカテーテル30を示す平面図、図4(B)は同カテーテル30の外管部の一部を剥離して示す平面図、図5(A)および(B)は同カテーテル30の製造過程を示す平面図である。

【0017】カテーテル30は、図4(A)および(B)に示すように、長さL₁のねじり剛性が比較的小なる先端部31と、長さL₂のねじり剛性が比較的小なる先端部32とが軸方向に一体形成されている。上記カ

4

テーテル30においては、本体部31における可塑性の内管部33と可塑性の外管部34との間に、一層からなる補強層35を介装し、先端部32を内管部33と外管部34の一体化状態によって形成している。ここで、補強層35は、本体部31における反先端部32側(基端側)の密に編まれたワイヤ層35Aと、本体部31における先端部32側の粗に編まれたワイヤ層35Bとから形成されている。ワイヤ層35Bの先端部32側の端部は、内管部33に接着されている。

【0018】上記カテーテル30によれば、前記カテーテル20と同様に、本体部31と先端部32とが一体形成され、ねじり剛性が大きくかつ先端部32に柔軟性を有し、本体部31と先端部32で外径が均一化されるとともに、比較的大なる内径を形成することが可能となる。特に、上記カテーテル30においては、本体部31における反先端部32側(基端側)の密に編まれたワイヤ層35Aと、本体部31における先端部32側の粗に編まれたワイヤ層35Bとによって、補強層35を形成したので、本体部31と先端部32のねじり剛性の変化をゆるやかなものとして、本体部31の回転に対する先端部32の応答性を速くするとともに、本体部31に対する先端部32の急な折れ曲がりを防止し、折れ曲がりに基づくカテーテル内部空間の閉塞発生を防止することが可能となる。また、上記カテーテル30においては、ワイヤ層35Bの先端部32側の端部を内管部33に接着したから、製造段階におけるワイヤ層35Bの内管部33からの剥離を防止することが可能となる。

【0019】次に、上記カテーテル30の製造方法について説明する。まず、可塑性の内管部33が押出し成形される。次に、内管部33の上面に、図5(A)に示すように補強層35を連続的に一層形成する。ここで、補強層35は、網の目が密(例えばピッチP₁=1mm)なワイヤ層35Aと、網の目が粗(例えばピッチP₁=10mm)なワイヤ層35Bとが交互に形成される。次に除去すべき一定区間のワイヤ層35Bの端部を内管部33に接着剤で接着した後上記ワイヤ層35Bの略中央部の一部を図5(B)に示すように除去する。次に、内管部33、ワイヤ層35A、35Bの上面に、可塑性の外管部34を押出し成形する。次にワイヤ層35Aのある部分の略中間部X₁と、補強層35のない部分の略中間部X₂で切断し、ワイヤ層35A、35Bのある部分を本体部31とし、補強層35のない部分を先端部32とするカテーテル30を得る。ここで、本実施例においては、「補強層35のある部分の中間部と補強層35のない部分の中間部を切断する」という従来全く見られなかった技術的事項を具備したから、補強層35のある部分と補強層35のない部分の境界部で切断する等と比して、補強層35をカテーテル30の本分連続形成でき、生産性を向上できるという格別のメリットがある。すなわち、上記製造方法によれば、カテーテル30を高い生産

Appendix B

(4)

特開平5-220225

5

性にて連続して形成可能となる。

【0020】図6(A)は本発明の第2実施例に係るカテーテル40を示す平面図、図6(B)は同カテーテル40の外管部の一部を剥離して示す平面図、図7(A)および(B)は同カテーテル40の製造過程を示す平面図である。

【0021】カテーテル40は、図6(A)および(B)に示すように、長さL₁のねじり剛性が比較的大なる本体部41と、長さL₂のねじり剛性が比較的小なる先端部42とが軸方向に一体形成されている。上記カテーテル40においては、本体部41における可撓性の内管部43と可撓性の外管部44との間に、一層からなる補強層45を介装し、先端部42を内管部43に外管部44の一体化状態によって形成している。ここで、補強層45は、本体部41における反先端部42側(基端側)の編まれたワイヤ層45Aと、本体部41における先端部42側の編まれないワイヤ層45Bとから形成されている。ワイヤ層45Bの先端部42側の端部は、内管部43に接着されている。編まれないワイヤ層45Bは、図7の通りカテーテル軸と平行に設けられている。

【0022】上記カテーテル40によれば、前記カテーテル20と同様に、本体部41と先端部42が一体形成され、ねじり剛性が大きくかつ先端部42に柔軟性を有し、本体部41と先端部42で外径が略均一化されるとともに、比較的大なる内径を形成することが可能となる。また、上記カテーテル40は、前記カテーテル30と同様に、本体部41と先端部42のねじり剛性の変化をゆるやかなものとして本体部41の回転に対する先端部42の応答性を速くするとともに、本体部41に対する先端部42の急な折れ曲がり防止可能となる。また、上記カテーテル40においては、ワイヤ層45Bの先端部42側の端部を内管部43に接着したから、製造段階におけるワイヤ層45Bの端部の内管部43からの剥離を防止することが可能となる。

【0023】次に、上記カテーテル40の製造方法について説明する。まず、可撓性の内管部43が押し出し成形される。次に、内管部43上に、図7(A)に示すように、補強層45を連続的に一層形成する。ここで、補強層45は編まれたワイヤ層45Aと、編まれない補強層45Bとが交互に形成される。次に、除去すべき一定区間のワイヤ層45Bの端部を内管部43に接着剤で接着した後上記ワイヤ層45Bの略中央部の一部を図7(B)に示すように除去する。次に、内管部43、ワイヤ層45A、45Bの上面に外管部44を押し出し成形する。次に、ワイヤ層45Aのある部分の略中間部X₁と、補強層45のない部分の略中間部X₂で切断し、ワ

6

イヤ層45A、45Bのある部分を本体部41とし、補強層45のない部分を先端部42とするカテーテル40を得る。ここで、本実施例においては、「補強層45のある部分の中間部と補強層45のない部分の中間部を切断する」という従来全く見られなかった技術的事項を具備したから、補強層45のある部分と補強層45のない部分の境界部で切断する等に比して、補強層45をカテーテル40の2本分連続形成でき、生産性を向上できるという格別のメリットがある。すなわち、上記製造方法によれば、カテーテル40を高い生産性にて連続して形成可能となる。

【0024】

【発明の効果】以上のように本発明によれば、本体部と先端部が一体形成され、ねじり剛性が大きくかつ先端部に柔軟性を有し、本体部と先端部で外径が略均一化されるときともに、比較的大なる内径を形成することができ、更に、本体部と先端部のねじり剛性の変化を緩やかなものとして、本体部の回転に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がり防止することができるカテーテルを提供することができる。

【図面の簡単な説明】

【図1】図1は一般のカテーテルを示す平面図である。

【図2】図2は従来例に係るカテーテルを示す一部切断図である。

【図3】図3は他の従来例に係るカテーテルを示す一部切断図である。

【図4】図4(A)は本発明の第1実施例に係るカテーテルを示す平面図、図4(B)は同カテーテルの外管部の一部を剥離して示す平面図である。

【図5】図5(A)および(B)は同カテーテルの製造過程を示す平面図である。

【図6】図6(A)は本発明の第2実施例に係るカテーテルを示す平面図、図6(B)は同カテーテルの外管部の一部を剥離して示す平面図である。

【図7】図7(A)および(B)は同カテーテルの製造過程を示す平面図である。

【符号の説明】

30、40 カテーテル

31、41 本体部

32、42 先端部

33、43 内管部

34、44 外管部

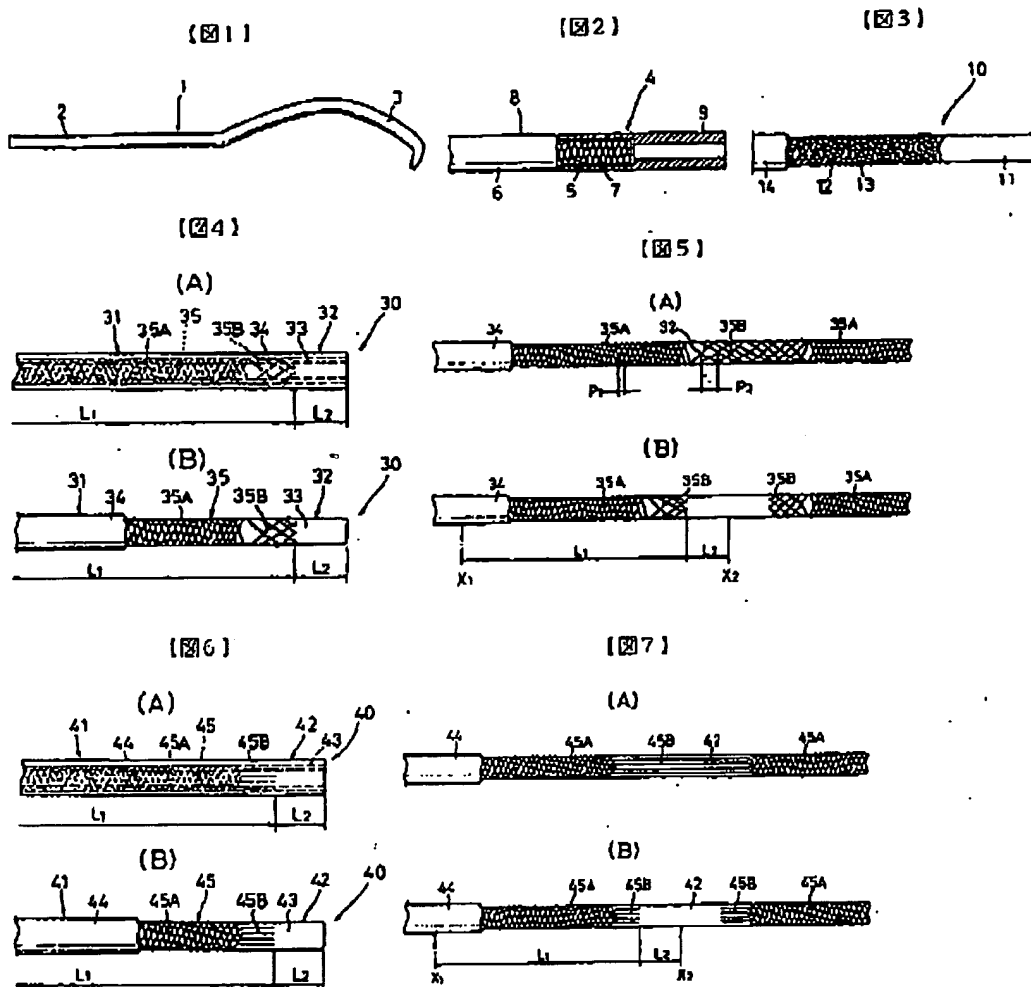
35、45 補強層

35A、35B、45A、45B ワイヤ層

Appendix B

(5)

特開平5-220225



Appendix B

JP5-220225-A



MACHINE-ASSISTED TRANSLATION (MAT):

(19)【発行国】 日本国特許庁 (JP)	(19)[ISSUING COUNTRY] Japan Patent Office (JP)
(12)【公報種別】 公開特許公報 (A)	(12)[GAZETTE CATEGORY] Laid-open Kokai Patent (A)
(11)【公開番号】 特開平 5 - 2 2 0 2 2 5	(11)[KOKAI NUMBER] Unexamined Japanese Patent Heisei 5-220225
(43)【公開日】 平成 5 年 (1 9 9 3) 8 月 3 1 日	(43)[DATE OF FIRST PUBLICATION] August 31, Heisei 5 (1993. 8.31)
(54)【発明の名称】 カテーテル	(54)[TITLE of the Invention] CATHETER
(51)【国際特許分類第 5 版】 A61M 25/00 306 B 7831-4C Z 7831-4C	(51)[IPC Int. Cl. 5] A61M 25/00 306 B 7831-4C Z 7831-4C
【審査請求】 有	[REQUEST FOR EXAMINATION] Yes
【発明の数】 3	[NUMBER OF INVENTIONS] 3
【全頁数】 5	[NUMBER OF PAGES] 5
(21)【出願番号】 特願平 3 - 2 3 6 9 4 0	(21)[APPLICATION NUMBER] Japanese Patent Application Heisei 3-236940
(22)【出願日】	(22)[DATE OF FILING]

10/16/2003

1/23

(C) DERWENT

Appendix B

JP5-220225-A



平成 3 年 (1 9 9 1) 8 月 2 6 August 26, Heisei 3 (1991. 8.26)
日

(71) 【出願人】

(71)[PATENTEE/ASSIGNEE]

【識別番号】

[ID CODE]

0 0 0 1 0 9 5 4 3

000109543

【氏名又は名称】

[NAME OR APPELLATION]

テルモ株式会社

Terumo CORP.

【住所又は居所】

[ADDRESS or DOMICILE]

東京都渋谷区幡ヶ谷 2 丁目 4 4
番 1 号

(72) 【発明者】

(72)[INVENTOR]

【氏名】

[NAME OR APPELLATION]

鈴木 龍夫

Suzuki Tatsuo

【住所又は居所】

[ADDRESS or DOMICILE]

神奈川県横浜市緑区霧が丘 6 丁
目 1 番地 1 - 1 2 - 1 0 5

(72) 【発明者】

(72)[INVENTOR]

【氏名】

[NAME OR APPELLATION]

松本 淳

Matsumoto Jyun

【住所又は居所】

[ADDRESS or DOMICILE]

東京都調布市若葉町 1 丁目 1 6
番地

(74) 【代理人】

(74)[AGENT]

【弁理士】

[PATENT ATTORNEY]

10/16/2003

2/23

(C) DERWENT

Appendix B

JP5-220225-A



【氏名又は名称】

塩川 修治

[NAME OR APPELLATION]

Shiokawa Shuji

(57) 【要約】

(57)[ABSTRACT of the Disclosure]

【目的】

本体部と先端部のねじり剛性の変化を緩やかなものとして、本体部の回動に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がりを防止することができるカテーテルを提供すること。

[PURPOSE]

Provide catheter which can prevent bending with sudden tip with respect to main-body section while making faster the response characteristic of tip with respect to rotation of main-body section for change of the torsional rigidity of main-body section and tip as a loose thing.

【構成】

基端から先端に至る内管部 33 と該内管部 33 を被覆する外管部 34 からなるカテーテル 30 であって、該カテーテル 30 は先端部 32 と本体部 31 を有し、該本体部 31 における内管部 33 と外管部 34 との間に一層からなる補強層 35 を介装し、かつ該先端部 32 は上記補強層 35 を有さず、更に前記補強層 35 は、本体部 31 における基端側の密に編まれたワイヤ層 35A と、本体部 31 における先端側の粗に編まれたワイヤ層 35B とからなるようにしたものである。

[CONSTITUTION]

It is catheter 30 which is made of inner-pipe section 33 which extends at front end from base end, and outer-tube section 34 which coats this inner-pipe section 33, comprised such that this catheter 30 has tip 32 and main-body section 31, reinforcement layer 35 which is made of one layer between inner-pipe sections 33 and outer-tube sections 34 in this main-body section 31 is interposed, and this tip 32 does not have the above-mentioned reinforcement layer 35.

Furthermore, said reinforcement layer 35 is made of wire layer 35B by which front-end side in wire layer 35A knitted densely and main-body section 31 by the side of base end in main-body section 31 was knitted roughly.

10/16/2003

3/23

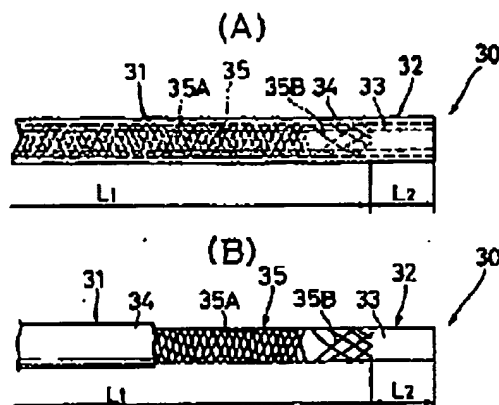
(C) DERWENT

Appendix B

JP5-220225-A

THOMSON

DERWENT



【特許請求の範囲】

[CLAIMS]

【請求項 1】

基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の密に編まれたワイヤ層と、本体部における先端側の粗に編まれたワイヤ層とからなることを特徴とするカテーテル。

[CLAIM 1]

It is catheter which is made of inner-pipe section which extends at front end from base end, and outer-tube section which coats this inner-pipe section, comprised such that this catheter has tip and main-body section, reinforcement layer which is made of one layer between inner-pipe sections and outer-tube sections in this main-body section is interposed, and this tip does not have the above-mentioned reinforcement layer.

Furthermore, said reinforcement layer is made of wire layer knitted densely by the side of base end in main-body section, and wire layer in which front-end side in main-body section was knitted roughly.

Catheter characterized by the above-mentioned.

【請求項 2】

[CLAIM 2]

10/15/2003

4/23

(C) DERWENT

Appendix B

JP5-220225-A



基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の編まれたワイヤ層と、本体部における先端側の編まれないワイヤ層とからなることを特徴とするカテーテル。

It is catheter which is made of outer-tube section which coats inner-pipe section which extends at front end from base end, and this inner-pipe section, comprised such that this catheter has tip and main-body section, reinforcement layer which is made of one layer between inner-pipe sections and outer-tube sections in this main-body section is interposed, and this tip does not have the above-mentioned reinforcement layer.

Furthermore, said reinforcement layer is made of wire layer in which base-end side in main-body section was knitted, and wire layer in which front-end side in main-body section is not knitted.

Catheter characterized by the above-mentioned.

【請求項3】

基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層の先端側の端部は、内管部に固定されていることを特徴とするカテーテル。

[CLAIM 3]

It is catheter which is made of outer-tube section which coats inner-pipe section which extends at front end from base end, and this inner-pipe section, comprised such that this catheter has tip and main-body section, reinforcement layer which is made of one layer between inner-pipe sections and outer-tube sections in this main-body section is interposed, and this tip does not have the above-mentioned reinforcement layer.

Furthermore, terminal portion by the side of front end of said reinforcement layer is fixed to inner-pipe section.

Catheter characterized by the above-mentioned.

【発明の詳細な説明】**[DETAILED DESCRIPTION of the**

10/16/2003

5/23

(C) DERWENT

Appendix B

JP5-220225-A



INVENTION]

【0001】

[0001]

【産業上の利用分野】
本発明はカテーテルに関する。

[INDUSTRIAL APPLICATION]
This invention relates to catheter.

【0002】

[0002]

【従来の技術】
図1に示すようなカテーテル1は、例えばガイドワイヤ等に導かれて、血管等体腔内に挿入され、その先端の方向を制御されつつ目的の部位に到達可能とされている。

[PRIOR ART]
Catheter 1 as shown in FIG. 1 is led for example, to guide wire etc., It is inserted in intra-corporeals, such as blood vessel, It is supposed at target part that it is reachable, the direction of the front end being controlled.

【0003】

[0003]

そこで、このカテーテル1には、本体部2の基部をねじってその先端部3を方向づけることが可能なように、大なるねじり剛性を有することが要求される。また、先端部3に目的部位に挿入容易な形状を容易に与えることが可能であり、挿入時の先端部3が血管等の挿入経路変化に沿って容易に変形して血管等の内壁に損傷を与えることがないように、先端部3に柔軟性が要求される。

So, this catheter 1 is required to have large torsional rigidity so that base of main-body section 2 may be twisted and that tip 3 can be oriented.
Moreover, flexibility is required of tip 3 so that easy shape of insertion to objective part can be easily given to tip 3, tip 3 at the time of insertion may change easily along insertion pathway change of blood vessel etc. and damage may not be done to inner walls, such as blood vessel.

【0004】

[0004]

図2は、先端部に柔軟性を有し、かつ大なるねじり剛性を有して

FIG. 2 has flexibility in tip, and it is partially broken figure which shows conventional

10/16/2003

6/23

(C) DERWENT

Appendix B

JP5-220225-A



なる従来のカテーテル4を示す一部破断図である。カテーテル4は、可撓性の内管部5と、可撓性の外管部6との間にワイヤ層7を介装することによってねじり剛性の大きな本体部8を形成している。更に、このカテーテル4は、上記本体部8の外管部6を一部除去した端部に比較的柔軟な先端部9を接続されている。

catheter 4 which has large torsional rigidity.

Catheter 4 forms large main-body section 8 of torsional rigidity by interposing wire layer 7 between flexible inner-pipe section 5 and flexible outer-tube section 6.

Furthermore, comparatively flexible tip 9 is connected to terminal portion at which this catheter 4 carried out partial elimination of the outer-tube section 6 of the above-mentioned main-body section 8.

[0005]

図3は、先端部に柔軟性を有し、かつ大きなねじり剛性を有してなる従来の他のカテーテル10を示す一部破断図である。このカテーテル10は、可撓性内管部11の基端から先端手前まで第1ワイヤ層12を形成され、その先端手前から折り返して再び基端まで第2ワイヤ層13を形成された後、内管部11および両ワイヤ層12、13の上面に可撓性外管部14を被覆されている。

[0005]

FIG. 3 has flexibility in tip, and it is partially broken figure which shows conventional other catheter 10 which has large torsional rigidity.

This catheter 10 has 1st wire layer 12 formed from base end of flexible inner-pipe section 11 to front-end foreground.

After repeating from the front-end foreground and forming 2nd wire layer 13 to base end again, flexible outer-tube section 14 is coated by upper face of inner-pipe section 11 and both wires layers 12 and 13.

[0006]

【発明が解決しようとする課題】

然しながら、上記カテーテル4にあつては、本体部8と先端部9との接続部に段差を生じ、血管等への挿入を円滑に行なうことが困難であり、血栓を生ずる

[0006]

[PROBLEM to be solved by the invention]

However, it is difficult to produce step in connection part of main-body section 8 and tip 9, and to perform insertion to blood vessel etc. smoothly by the above-mentioned catheter 4.

There is a possibility of generating thrombosis. Moreover, there is a possibility of generating

10/16/2003

7/23

(C) DERWENT

Appendix B

JP5-220225-A



虞れがある。また、本体部 8 と先端部 9 との接続不良により、両者間で離脱を生ずる虞れがある。

detachment among both, by inferior connection of main-body section 8 and tip 9.

[0007]

また、上記カテーテル 10 は、本体部を構成する内管部 11 と外管部 14 との間に、二層の第 1 ワイヤ層 12 および第 2 ワイヤ層 13 からなる補強層が介装されていることから、補強層の厚みが大となり、カテーテルが挿入される血管等の挿入路内径により定まる所定のカテーテル外径下で、カテーテル内径が小となる。また、上記補強層の厚みが大であることから、本体部のカテーテル外径と先端部のカテーテル外径との間に比較的大なる段差を生じ、血管等への挿入を行なうことが困難となる。また、上記カテーテル 10 は、本体部を構成する内管部 11 の上面で、第 1 ワイヤ層 12 および第 2 ワイヤ層 13 を折り返すことによって形成しているもので、その全体を連続して形成し、カテーテル用基材を得ることができない。

[0007]

Moreover, thickness of reinforcement layer since it interposes reinforcement layer which is made of two layers 1st wire layer 12 and 2nd wire layer 13 between inner-pipe sections 11 and outer-tube sections 14 which comprise main-body section of the above-mentioned catheter 10 is large next door, under fixed catheter outer diameter which becomes settled with insertion path internal diameters, such as blood vessel in which catheter is inserted, catheter internal diameter constitutes smallness.

Moreover, since thickness of the above-mentioned reinforcement layer is great, large step is comparatively produced between catheter outer diameter of main-body section, and catheter outer diameter of tip, and it becomes difficult to perform insertion to blood vessel etc.

Moreover, the above-mentioned catheter 10 is upper face of inner-pipe section 11 which comprises main-body section, and is formed by repeating 1st wire layer 12 and 2nd wire layer 13.

Therefore, the whole is formed continuously, base material for catheters cannot be obtained.

[0008]

また、カテーテルにあつては、血管体腔内への挿入作業性を向

[0008]

Moreover, by catheter, in order to improve insertion operativity to blood-vessel

10/16/2003

8/23

(C) DERWENT

Appendix B

JP5-220225-A

THOMSON

DERWENT

上するために、本体部と先端部のねじり剛性の変化を緩やかなものをして、本体部の回転に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がり防止可能とすることが望まれる。

intra-corporeal, loose thing is carried out for change of the torsional rigidity of main-body section and tip.

While making faster the response characteristic of tip with respect to rotation of main-body section, to enable prevention of bending with sudden tip with respect to main-body section is desired.

【0009】

本発明は、本体部と先端部が一体形成され、ねじり剛性が大きくかつ先端部に柔軟性を有し、本体部と先端部で外径が略均一化されるとともに、比較的大なる内径を形成することができ、更に、本体部と先端部のねじり剛性の変化を緩やかなものとして、本体部の回転に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がり防止することができ、カテーテルを提供することを目的とする。

[0009]

Integral formation of main-body section and the tip is carried out, torsional rigidity is large and this invention has flexibility in tip, while outer diameter is roughly homogenized by main-body section and tip, large internal diameter can be formed comparatively, furthermore, while making faster the response characteristic of tip with respect to rotation of main-body section for change of the torsional rigidity of main-body section and tip as a loose thing, bending with sudden tip with respect to main-body section can be prevented.

It aims at providing such a catheter.

【0010】

【課題を解決するための手段】
請求項1に記載の本発明は、基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記

[0010]

[MEANS to solve the Problem]

This invention of Claim 1 is a catheter which is made of outer-tube section which coats inner-pipe section which extends at front end from base end, and this inner-pipe section, comprised such that this catheter has tip and main-body section, reinforcement layer which is made of one layer between inner-pipe sections and outer-tube sections in this main-body

10/16/2003

9/23

(C) DERWENT

Appendix B

JP5-220225-A



補強層を有さず、更に前記補強層は、本体部における基端側の密に編まれたワイヤ層と、本体部における先端側の粗に編まれたワイヤ層とからなるようにしたものである。

section is interposed, and this tip does not have the above-mentioned reinforcement layer.

Furthermore, said reinforcement layer is made of wire layer knitted densely by the side of base end in main-body section, and wire layer in which front-end side in main-body section was knitted roughly.

【0011】

請求項2に記載の本発明は、基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層は、本体部における基端側の編まれたワイヤ層と、本体部における先端側の編まれないワイヤ層とからなるようにしたものである。

[0011]

This invention of Claim 2 is a catheter which is made of outer-tube section which coats inner-pipe section which extends at front end from base end, and this inner-pipe section, comprised such that this catheter has tip and main-body section, reinforcement layer which is made of one layer between inner-pipe sections and outer-tube sections in this main-body section is interposed, and this tip does not have the above-mentioned reinforcement layer.

Furthermore, said reinforcement layer is made of wire layer in which base-end side in main-body section was knitted, and wire layer in which front-end side in main-body section is not knitted.

【0012】

請求項3に記載の本発明は、基端から先端に至る内管部と該内管部を被覆する外管部からなるカテーテルであって、該カテーテルは先端部と本体部を有し、該本体部における内管部と外管部との間に一層からなる補強層を介装し、かつ該先端部は上記補強層を有さず、更に前記補強層の先端側の端部は、内管部に

[0012]

This invention of Claim 3 is a catheter which is made of outer-tube section which coats inner-pipe section which extends at front end from base end, and this inner-pipe section, comprised such that this catheter has tip and main-body section, reinforcement layer which is made of one layer between inner-pipe sections and outer-tube sections in this main-body section is interposed, and this tip does not have the above-mentioned reinforcement layer.

10/16/2003

10/23

(C) DERWENT

Appendix B

JP5-220225-A



固定されているようにしたもの
である。尚、ここで言う「固定」
は、補強層の先端側の端部を内
管部に接着剤により接着するほ
か、熱をかけて内管に融着、更
には補強層であるワイヤ層を内
管に埋設することも含めるもの
とする。

Furthermore, terminal portion by the side of
front end of said reinforcement layer is fixed to
inner-pipe section.

In addition, "fixation" said here attaches
terminal portion by the side of front end of
reinforcement layer on inner-pipe section with
adhesive.

And it shall also include applying heat, fusing to
inner pipe or burying under the inner pipe wire
layer which is reinforcement layer.

【0013】

[0013]

【作用】

本発明によれば、下記(1)～(3)
の作用効果がある。

(1)カテーテルは先端部と本体
部を有し、該本体部における内
管部と外管部との間に一層から
なる補強層を介装し、かつ該先
端部は上記補強層を有していな
いようにしたので、本体部と先
端部が一体形成され、ねじり剛
性が大きくかつ先端部に柔軟性
を有し、本体部と先端部で外径
が均一化されるとともに比較的
大なる内径を形成することが可
能となる。

【OPERATION】

According to this invention, there is effect of
following (1)-(3).

(1) Catheter has tip and main-body section,
reinforcement layer which is made of one layer
between inner-pipe sections and outer-tube
sections in this main-body section is interposed,
and since this tip was kept from having the
above-mentioned reinforcement layer, integral
formation of main-body section and the tip is
carried out, torsional rigidity has flexibility in tip
greatly, while outer diameter is homogenized by
main-body section and tip, large internal
diameter can be formed comparatively.

【0014】

[0014]

(2)補強層を密と粗の2段階、或
いは編まれたものと編まれない
ものとの2段階にて構成するよ
うにしたので、本体部と先端部
のねじり剛性の変化を緩やかな
ものとして本体部の回転に対す

(2) Reinforcement layer consisted of rough
2-step or 2-step of what is knitted, and thing
which is not knitted with it being dense.
Therefore, while making loose change of the
torsional rigidity of main-body section and tip
and making faster the response characteristic of

10/16/2003

11/23

(C) DERWENT

Appendix B

JP5-220225-A

THOMSON

DERWENT

る先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がり防止することが可能となる。

tip with respect to rotation of main-body section, bending with sudden tip with respect to main-body section can be prevented.

【0015】

(3)補強層の先端側の端部が、内管部に固定されてなるものとするにより、製造段階における補強層端部の内管部からの剥離を防止することが可能となる。

[0015]

(3) Terminal portion by the side of front end of reinforcement layer can prevent exfoliation from inner-pipe section of reinforcement layer-edge section in manufacture phase by coming to be fixed to inner-pipe section.

【0016】

【実施例】

図4(A)は本発明の第1実施例に係るカテーテル30を示す平面図、図4(B)は同カテーテル30の外管部の一部を剥離して示す平面図、図5(A)および(B)は同カテーテル30の製造過程を示す平面図である。

[0016]

[EXAMPLES]

FIG.4(A) is a top view which shows catheter 30 based on 1st Example of this invention, FIG.4(B) is a top view which exfoliates and shows one part of outer-tube section of this catheter 30, FIG.5(A) and (B) are top views which show manufacture process of this catheter 30.

【0017】

カテーテル30は、図4(A)および(B)に示すように、長さ L_1 のねじり剛性が比較的小なる先端部31と、長さ L_2 のねじり剛性が比較的小なる先端部32とが軸方向に一体形成されている。上記カテーテル30にあつては、本体部31における可撓性の内管部33と可撓性の外管部34との間に、一層か

[0017]

Catheter 30 is as shown in FIG.4(A) and (B), with small tip 31, length L_1 torsional rigidity is comparatively, length L_2 torsional rigidity is with small tip 32 comparatively.

Integral formation of these is carried out at axial direction.

By the above-mentioned catheter 30, reinforcement layer 35 which is made of one layer between flexible inner-pipe section 33 in main-body section 31 and flexible outer-tube

10/16/2003

12/23

(C) DERWENT

Appendix B

JP5-220225-A



らなる補強層 35 を介装し、先端部 32 を内管部 33 と外管部 34 の一体化状態によって形成している。ここで、補強層 35 は、本体部 31 における反先端部 32 側（基端側）の密に編まれたワイヤ層 35A と、本体部 31 における先端部 32 側の粗に編まれたワイヤ層 35B とから形成されている。ワイヤ層 35B の先端部 32 側の端部は、内管部 33 に接着されている。

【0018】

上記カテーテル 30 によれば、前記カテーテル 20 と同様に、本体部 31 と先端部 32 とが一体形成され、ねじり剛性が大きくかつ先端部 32 に柔軟性を有し、本体部 31 と先端部 32 で外径が略均一化されるとともに、比較的大なる内径を形成することが可能となる。特に、上記カテーテル 30 にあっては、本体部 31 における反先端部 32 側（基端側）の密に編まれたワイヤ層 35A と、本体部 31 における先端部 32 側の粗に編まれたワイヤ層 35B とによって、補強層 35 を形成したので、本体部 31 と先端部 32 のねじり剛性の変化をゆるやかなものとして、本体部 31 の回転に対する先端部 32 の応答性を速くするとともに、本体部 31 に対する先端部 32 の急な折れ曲が

section 34 is interposed, tip 32 is formed according to unification state of inner-pipe section 33 and outer-tube section 34.

Here, reinforcement layer 35 is formed from wire layer 35B by which tip 32 side in wire layer 35A knitted densely and main-body section 31 by the side of anti-tip 32 in main-body section 31 (base-end side) was knitted roughly.

Terminal portion by the side of tip 32 of wire layer 35B is attached on inner-pipe section 33.

【0018】

According to the above-mentioned catheter 30, integral formation of main-body section 31 and tip 32 is carried out like said catheter 20, torsional rigidity has flexibility in tip 32 greatly, while outer diameter is roughly homogenized by main-body section 31 and tip 32, large internal diameter can be formed comparatively. In particular, it is with the above-mentioned catheter 30, since reinforcement layer 35 was formed by wire layer 35B by which tip 32 side in wire layer 35A knitted densely and main-body section 31 by the side of anti-tip 32 in main-body section 31 (base-end side) was knitted roughly, while making loose change of the torsional rigidity of main-body section 31 and tip 32 and making faster the response characteristic of tip 32 with respect to rotation of main-body section 31, sudden bending of tip 32 with respect to main-body section 31 is prevented, obstruction generating of catheter interior space based on bending can be prevented.

10/16/2003

13/23

(C) DERWENT

Appendix B

JP5-220225-A



りを防止し、折れ曲がりに基づ
くカテーテル内部空間の閉塞発
生を防止することが可能とな
る。また、上記カテーテル 30
にあっては、ワイヤ層 35B の
先端部 32 側の端部を内管部 3
3 に接着したから、製造段階に
おけるワイヤ層 35B の内管部
33 からの剥離を防止すること
が可能となる。

Moreover, by the above-mentioned catheter 30,
since terminal portion by the side of tip 32 of
wire layer 35B was attached on inner-pipe
section 33, exfoliation from inner-pipe section
33 of wire layer 35B in manufacture phase can
be prevented.

【0019】

次に、上記カテーテル 30 の製
造方法について説明する。まず、
可撓性の内管部 33 が押出し成
形される。次に、内管部 33 の
上面に、図 5 (A) に示すよう
に補強層 35 を連続的に一層形
成する。ここで、補強層 35 は、
網の目が密（例えばピッチ P_1
= 1mm）なワイヤ層 35A と、
網の目が粗（例えばピッチ P_2
= 10mm）なワイヤ層 35B と
が交互に形成される。次に除去
すべき一定区間のワイヤ層 35
B の端部を内管部 33 に接着剤
で接着した後上記ワイヤ層 35
B の略中央部の一部を図 5 (B)
に示すように除去する。次に、
内管部 33、ワイヤ層 35A、
35B の上面に、可撓性の外管
部 34 を押出し成形する。次に
ワイヤ層 35A のある部分の略
中間部 X_1 と、補強層 35 のな
い部分の略中間部 X_2 で切断
し、ワイヤ層 35A、35B の

【0019】

Next, manufacturing method of the
above-mentioned catheter 30 is demonstrated.
First, extrusion molding of the flexible inner-pipe
section 33 is carried out.

Next, reinforcement layer 35 is continuously
formed further in upper face of inner-pipe
section 33 as shown in FIG.5(A).

Here, as for reinforcement layer 35, wire layer
35A with dense (for example, pitch P_1 = 1 mm)
meshes of a net and wire layer 35B with rough
(for example, pitch P_2 = 10 mm) meshes of a net
are formed alternately.

Next, after attaching with adhesive terminal
portion of wire layer 35B of fixed area which
should be removed on inner-pipe section 33,
one part of nearly central section of the
above-mentioned wire layer 35B is removed as
shown in FIG.5(B).

Next, extrusion molding of the flexible
outer-tube section 34 is carried out to upper
face of inner-pipe section 33 and wire layers
35A and 35B.

Next, it cuts by nearly-middle section X_1 of part
with wire layer 35A, and nearly-middle section

10/16/2003

14/23

(C) DERWENT

Appendix B

JP5-220225-A

THOMSON

DERWENT

ある部分を本体部 31 とし、補強層 35 のない部分を先端部 32 とするカテーテル 30 を得る。ここで、本実施例にあっては、「補強層 35 のある部分の中間部と補強層 35 のない部分の中間部を切断する」という従来全く見られなかった技術的事項を具備したから、補強層 35 のある部分と補強層 35 のない部分の境界部で切断する等に比して、補強層 35 をカテーテル 30 の 2 本分連続形成でき、生産性を向上できるという格別のメリットがある。すなわち、上記製造方法によれば、カテーテル 30 を高い生産性にて連続して形成可能となる。

X₂ of part without reinforcement layer 35, let part with wire layers 35A and 35B be main-body section 31, catheter 30 which uses part without reinforcement layer 35 as tip 32 is obtained.

It compares with cutting in limit section of part with reinforcement layer 35, and part without reinforcement layer 35, since technical matter which is referred to as "Cutting intermediate part of part with reinforcement layer 35 and intermediate part of part without reinforcement layer 35" and which formerly was not seen at all was comprised in this Example here etc., and is catheter 30 about reinforcement layer 35. 2 duty continuous formation can be carried out and there is exceptional merit that productivity can be improved.

That is, according to the above-mentioned manufacturing method, catheter 30 can be continuously formed for high productivity.

【0020】

図 6 (A) は本発明の第 2 実施例に係るカテーテル 40 を示す平面図、図 6 (B) は同カテーテル 40 の外管部の一部を剥離して示す平面図、図 7 (A) および (B) は同カテーテル 40 の製造過程を示す平面図である。

[0020]

FIG.6(A) is a top view which shows catheter 40 based on 2nd Example of this invention, FIG.6(B) is a top view which exfoliates and shows one part of outer-tube section of this catheter 40, FIG.7(A) and (B) are top views which show manufacture process of this catheter 40.

【0021】

カテーテル 40 は、図 6 (A) および (B) に示すように、長さ L₁ のねじり剛性が比較的大なる本体部 41 と、長さ L₂ のねじり剛性が比較的小なる先端

[0021]

Catheter 40 is as shown in FIG.6(A) and (B), with large main-body section 41, the torsional rigidity of length L₁ is comparatively, the torsional rigidity of length L₂ is with small tip 42 comparatively.

10/16/2003

15/23

(C) DERWENT

Appendix B

JP5-220225-A

THOMSON

DERWENT

部 4 2 とが軸方向に一体形成されている。上記カテーテル 4 0 にあつては、本体部 4 1 における可撓性の内管部 4 3 と可撓性の外管部 4 4 との間に、一層からなる補強層 4 5 を介装し、先端部 4 2 を内管部 4 3 に外管部 4 4 の一体化状態によって形成している。ここで、補強層 4 5 は、本体部 4 1 における反先端部 4 2 側（基端側）の編まれたワイヤ層 4 5 A と、本体部 4 1 における先端部 4 2 側の編まれないワイヤ層 4 5 B とから形成されている。ワイヤ層 4 5 B の先端部 4 2 側の端部は、内管部 4 3 に接着されている。編まれないワイヤ層 4 5 B は、図 7 の通りカテーテル軸と平行に設けられている。

【0022】

上記カテーテル 4 0 によれば、前記カテーテル 2 0 と同様に、本体部 4 1 と先端部 4 2 が一体形成され、ねじり剛性が大きくかつ先端部 4 2 に柔軟性を有し、本体部 4 1 と先端部 4 2 で外径が略均一化されるとともに、比較的大なる内径を形成することが可能となる。また、上記カテーテル 4 0 は、前記カテーテル 3 0 と同様に、本体部 4 1 と先端部 4 2 のねじり剛性の変化をゆるやかなものとして本体部 4 1 の回転に対する先端部

Integral formation of these is carried out at axial direction.

By the above-mentioned catheter 40, reinforcement layer 45 which is made of one layer between flexible inner-pipe section 43 in main-body section 41 and flexible outer-tube section 44 is interposed, tip 42 is formed in inner-pipe section 43 according to unification state of outer-tube section 44.

Here, reinforcement layer 45 is formed from wire layer 45A by which anti-tip 42 side (base-end side) in main-body section 41 was knitted, and wire layer 45B by which tip 42 side in main-body section 41 is not knitted.

Terminal portion by the side of tip 42 of wire layer 45B is attached on inner-pipe section 43.

Wire layer 45B which is not knitted is provided in catheter axis and parallel as FIG. 7.

[0022]

According to the above-mentioned catheter 40, integral formation of main-body section 41 and tip 42 is carried out like said catheter 20, torsional rigidity has flexibility in tip 42 greatly, while outer diameter is roughly homogenized by main-body section 41 and tip 42, large internal diameter can be formed comparatively.

Moreover, like said catheter 30, while the above-mentioned catheter 40 makes faster the response characteristic of tip 42 with respect to rotation of main-body section 41 for change of the torsional rigidity of main-body section 41 and tip 42 as a loose thing, it can prevent sudden bending of tip 42 with respect to

10/18/2003

16/23

(C) DERWENT

Appendix B

JP5-220225-A



42の応答性を速くするとともに、本体部41に対する先端部42の急な折れ曲がり防止可能となる。また、上記カテーテル40にあっては、ワイヤ層45Bの先端部42側の端部を内管部43に接着したから、製造段階におけるワイヤ層45Bの端部の内管部43からの剥離を防止することが可能となる。

【0023】

次に、上記カテーテル40の製造方法について説明する。まず、可撓性の内管部43が押出し成形される。次に、内管部43上に、図7(A)に示すように、補強層45を連続的に一層形成する。ここで、補強層45は編まれたワイヤ層45Aと、編まれない補強層45Bとが交互に形成される。次に、除去すべき一定区間のワイヤ層45Bの端部を内管部43に接着剤で接着した後上記ワイヤ層45Bの略中央部の一部を図7(B)に示すように除去する。次に、内管部43、ワイヤ層45A、45Bの上面に外管部44を押出し成形する。次に、ワイヤ層45Aのある部分の略中間部X₁と、補強層45のない部分の略中間部X₂で切断し、ワイヤ層45A、45Bのある部分を本体部41とし、補強層45のない部分を先端部42とするカテ

main-body section 41.

Moreover, by the above-mentioned catheter 40, since terminal portion by the side of tip 42 of wire layer 45B was attached on inner-pipe section 43, exfoliation from inner-pipe section 43 of terminal portion of wire layer 45B in manufacture phase can be prevented.

[0023]

Next, manufacturing method of the above-mentioned catheter 40 is demonstrated. First, extrusion molding of the flexible inner-pipe section 43 is carried out.

Next, reinforcement layer 45 is continuously formed further as shown in FIG.7(A) on inner-pipe section 43.

Here, wire layer 45A by which reinforcement layer 45 was knitted, and reinforcement layer 45B which is not knitted are formed alternately.

Next, after attaching with adhesive terminal portion of wire layer 45B of fixed area which should be removed on inner-pipe section 43, one part of nearly central section of the above-mentioned wire layer 45B is removed as shown in FIG.7(B).

Next, extrusion molding of the outer-tube section 44 is carried out to upper face of inner-pipe section 43 and wire layers 45A and 45B.

Next, it cuts by nearly-middle section X₁ of part with wire layer 45A, and nearly-middle section X₂ of part without reinforcement layer 45, let part with wire layers 45A and 45B be main-body

10/16/2003

17/23

(C) DERWENT

Appendix B

JP5-220225-A



ーテル40を得る。ここで、本実施例にあつては、「補強層45のある部分の中間部と補強層45のない部分の中間部を切断する」という従来全く見られなかった技術的事項を具備したから、補強層45のある部分と補強層45のない部分の境界部で切断する等に比して、補強層45をカテーテル40の2本分連続形成でき、生産性を向上できるという格別のメリットがある。すなわち、上記製造方法によれば、カテーテル40を高い生産性にて連続して形成可能となる。

【0024】

【発明の効果】

以上のように本発明によれば、本体部と先端部が一体形成され、ねじり剛性が大きくかつ先端部に柔軟性を有し、本体部と先端部で外径が略均一化されるときともに、比較的大なる内径を形成することができ、更に、本体部と先端部のねじり剛性の変化を緩やかなものとして、本体部の回転に対する先端部の応答性を速くするとともに、本体部に対する先端部の急な折れ曲がり防止を防止することができるカテーテルを提供することができる。

10/16/2003

section 41, catheter 40 which uses part without reinforcement layer 45 as tip 42 is obtained.

It compares with cutting in limit section of part with reinforcement layer 45, and part without reinforcement layer 45, since technical matter which is referred to as "Cutting Intermediate part of part with reinforcement layer 45 and intermediate part of part without reinforcement layer 45" and which formerly was not seen at all was comprised in this Example here etc., and is catheter 40 about reinforcement layer 45. 2 duty continuous formation can be carried out and there is exceptional merit that productivity can be improved.

That is, according to the above-mentioned manufacturing method, catheter 40 can be continuously formed for high productivity.

【0024】

【ADVANTAGE of the invention】

As mentioned above, according to this invention, integral formation of main-body section and the tip is carried out, and torsional rigidity has flexibility in tip greatly, while outer diameter is roughly homogenized by main-body section and tip, large internal diameter can be formed comparatively, furthermore, while making faster the response characteristic of tip with respect to rotation of main-body section for change of the torsional rigidity of main-body section and tip as a loose thing, bending with sudden tip with respect to main-body section can be prevented.

Such a catheter can be provided.

18/23

(C) DERWENT

Appendix B

JP5-220225-A



【図面の簡単な説明】

[BRIEF DESCRIPTION OF THE DRAWINGS]

【図 1】

図 1 は一般のカテーテルを示す平面図である。

[FIG. 1]

FIG. 1 is a top view which shows common catheter.

【図 2】

図 2 は従来例に係るカテーテルを示す一部破断図である。

[FIG. 2]

FIG. 2 is a partially broken figure which shows catheter based on prior art example.

【図 3】

図 3 は他の従来例に係るカテーテルを示す一部破断図である。

[FIG. 3]

FIG. 3 is a partially broken figure which shows catheter based on other prior art example.

【図 4】

図 4 (A) は本発明の第 1 実施例に係るカテーテルを示す平面図、図 4 (B) は同カテーテルの外管部の一部を剥離して示す平面図である。

[FIG. 4]

FIG.4(A) is a top view which shows catheter based on 1st Example of this Invention, FIG.4(B) is a top view which exfoliates and shows one part of outer-tube section of this catheter.

【図 5】

図 5 (A) および (B) は同カテーテルの製造過程を示す平面図である。

[FIG. 5]

FIG.5(A) and (B) are top views which show manufacture process of this catheter.

【図 6】

図 6 (A) は本発明の第 2 実施例に係るカテーテルを示す平面図、図 6 (B) は同カテーテルの外管部の一部を剥離して示す平面図である。

[FIG. 6]

FIG.6(A) is a top view which shows catheter based on 2nd Example of this invention, FIG.6(B) is a top view which exfoliates and shows one part of outer-tube section of this catheter.

【図 7】

[FIG. 7]

10/16/2003

19/23

(C) DERWENT

Appendix B

JP5-220225-A

THOMSON

DERWENT

図7 (A) および (B) は同カ FIG.7(A) and (B) are top views which show
 テーテルの製造過程を示す平面 manufacture process of this catheter.
 図である。

【符号の説明】

30、40 カテーテル
 31、41 本体部
 32、42 先端部
 33、43 内管部
 34、44 外管部
 35、45 補強層
 35A、35B、45A、45B ワイヤ層
 B ワイヤ層

[Description of Symbols]

30, 40 Catheter
 31, 41 Main-body section
 32, 42 Tip
 33, 43 Inner-pipe section
 34, 44 Outer-tube section
 35, 45 Reinforcement layer
 35A, 35B, 45A, 45B Wire layer

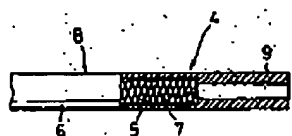
【図1】

[FIG. 1]



【図2】

[FIG. 2]



【図3】

[FIG. 3]

10/16/2003

20/23

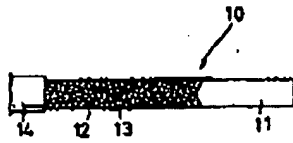
(C) DERWENT

Appendix B

JP5-220225-A

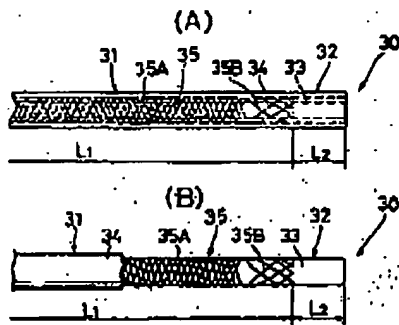
THOMSON

DERWENT



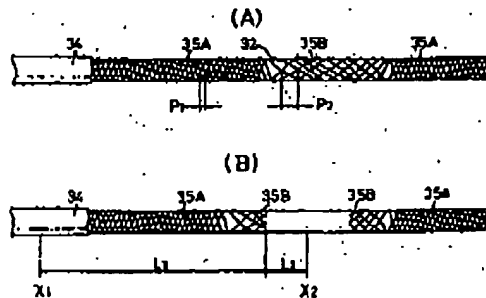
【図 4】

[FIG. 4]



【図 5】

[FIG. 5]



10/16/2003

21/23

(C) DERWENT

Appendix B

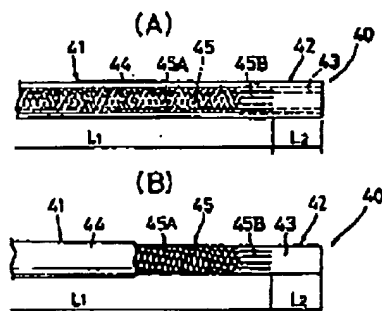
JP5-220225-A

THOMSON

DERWENT

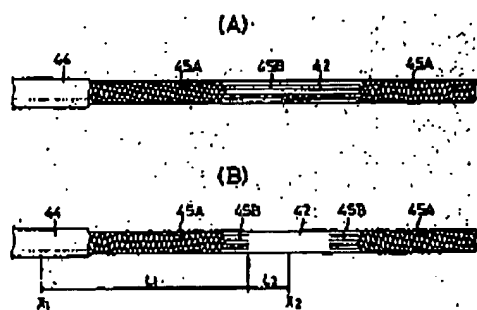
【図 6】

[FIG. 6]



【図 7】

[FIG. 7]



10/16/2003

22/23

(C) DERWENT

Appendix B

JP5-220225-A

**DERWENT TERMS AND CONDITIONS**

Derwent shall not in any circumstances be liable or responsible for the completeness or accuracy of any Derwent translation and will not be liable for any direct, indirect, consequential or economic loss or loss of profit resulting directly or indirectly from the use of any translation by any customer.

Derwent Information Ltd. is part of The Thomson Corporation

Please visit our home page:

["WWW.DERWENT.CO.UK"](http://WWW.DERWENT.CO.UK) (English)

["WWW.DERWENT.CO.JP"](http://WWW.DERWENT.CO.JP) (Japanese)

[JP,05-220225,A]

* NOTICES *

Japan Patent Office is not responsible for any damages caused by the use of this translation.

1. This document has been translated by computer. So the translation may not reflect the original precisely.
2. **** shows the word which can not be translated.
3. In the drawings, any words are not translated.

CLAIMS

[Claim(s)]

[Claim 1] It is the catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] The catheter characterized by consisting of a wire layer knit by ** by the side of the tip in the wire layer knit densely and the body section by the side of the end face in the body section.

[Claim 2] It is the catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] The catheter characterized by consisting of a wire layer in which the end face side in the body section was knit, and a wire layer in which the tip side in the body section is not knit.

[Claim 3] between inner tube parts and outer tube parts -- much more -- since -- the catheter which the becoming reinforcement layer is infixed, and this point does not have the above-mentioned reinforcement layer, but is further characterized by to fix the edge by the side of the tip of said reinforcement layer to an inner tube part. [in / it is the catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part, and this catheter has a point and the body section, and / this body section]

DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Industrial Application] This invention relates to a catheter.

[0002]

[Description of the Prior Art] The catheter 1 as shown in drawing 1 is led to a guidewire etc., and is inserted into coelomata, such as a blood vessel, and attainment of it to the target part is enabled, the direction of the tip being controlled.

[0003] So, this catheter 1 is required to have the torsional rigidity which becomes size so that it

Appendix C

may be possible to twist the base of the body section 2 and to orient that point 3. moreover, the point 3 -- the purpose part -- insertion -- it is possible to give an easy configuration easily, and flexibility is required of a point 3 so that the point 3 at the time of insertion may deform easily along with insertion path change of a blood vessel etc. and damage may not be done to walls, such as a blood vessel.

[0004] drawing 2 -- a point -- flexibility -- having -- and -- size -- the conventional catheter 4 which comes to have torsional rigidity is shown -- it is a fracture Fig. a part. The catheter 4 forms the body section 8 which is torsional rigidity and which becomes size by infixing the wire layer 7 between the flexible inner tube part 5 and the flexible outer tube part 6. Furthermore, the comparatively flexible point 9 is connected to the edge at which this catheter 4 removed the outer tube part 6 of the above-mentioned body section 8 in part.

[0005] drawing 3 -- a point -- flexibility -- having -- and -- size -- other conventional catheters 10 which come to have torsional rigidity are shown -- it is a fracture Fig. a part. After this catheter 10 had the 1st wire layer 12 formed from the end face of the flexible inner tube part 11 to tip this side, and it turns it up from that tip this side and it has the 2nd wire layer 13 again formed to a end face, it is having the flexible outer tube part 14 covered by the top face of an inner tube part 11 and both the wire layers 12 and 13.

[0006]

[Problem(s) to be Solved by the Invention] However, if it is in the above-mentioned catheter 4, a level difference is produced in the connection of the body section 8 and a point 9, it is difficult to perform insertion to a blood vessel etc. smoothly, and there is a possibility of producing a thrombus. Moreover, there is a possibility of producing balking among both, according to the faulty connection of the body section 8 and a point 9.

[0007] Moreover, since the reinforcement layer which consists of the 1st wire layer 12 and the 2nd wire layer 13 of a bilayer between the inner tube parts 11 and outer tube parts 14 from which the above-mentioned catheter 10 constitutes the body section is infixed, a catheter bore serves as smallness under the predetermined catheter outer diameter in which the thickness of a reinforcement layer becomes settled with insertion way bores, such as a blood vessel in which a large next door and a catheter are inserted. Moreover, since the thickness of the above-mentioned reinforcement layer is size, the level difference which comes size comparatively between the catheter outer diameter of the body section and the catheter outer diameter of a point is produced, and it becomes difficult to perform insertion to a blood vessel etc. Moreover, the above-mentioned catheter 10 is the top face of the inner tube part 11 which constitutes the body section, since it forms by turning up the 1st wire layer 12 and the 2nd wire layer 13, cannot form the whole continuously and cannot obtain the base material for catheters.

[0008] Moreover, while carrying out a loose thing for change of the torsional rigidity of the body section and a point and making quick responsibility of the point to rotation of the body section in order to improve the insertion workability into a blood vessel coelome if it is in a catheter, to enable prevention of sudden a point bending to the body section is desired.

[0009] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point, this invention While being able to form the bore which becomes size comparatively and making quick further responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing The purpose is carried out for offering the catheter which can prevent that sudden a point bends to the body section.

Appendix C

[0010]

[Means for Solving the Problem] This invention according to claim 1 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer knit by ** by the side of the tip in the wire layer knit densely and the body section by the side of the end face in the body section.

[0011] This invention according to claim 2 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer in which the end face side in the body section was knit, and a wire layer in which the tip side in the body section is not knit.

[0012] between inner tube parts and outer tube parts -- much more -- since -- the becoming reinforcement layer is infixed, this point does not have the above-mentioned reinforcement layer, but the edge by the side of the tip of said reinforcement layer is being further fixed to the inner tube part. [in / this invention according to claim 3 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part, and this catheter has a point and the body section, and / this body section] In addition, "immobilization" said here shall paste up the edge by the side of the tip of a reinforcement layer on an inner tube part with adhesives, and also laying under the inner tube welding and the wire layer which is a reinforcement layer further at an inner tube, applying heat shall include it.

[0013]

[Function] According to this invention, there is the operation effectiveness of the following ** -

** between inner tube parts and outer tube parts -- much more -- since -- since the becoming reinforcement layer is infixed and it was made for this point not to have the above-mentioned reinforcement layer, while the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and an outer diameter is equalized by the body section and the point -- comparatively -- size -- it becomes possible to form a bore. [in / a catheter has a point and the body section and / this body section]

[0014] ** Since the reinforcement layer was constituted from two steps of what is not knit with two steps or the knit thing of ** as it is dense, while making quick responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing, it becomes possible to prevent that sudden a point bends to the body section.

[0015] ** The edge by the side of the tip of a reinforcement layer becomes possible [preventing the exfoliation from the inner tube part of the reinforcement layer edge in a manufacture phase] by coming to be fixed to an inner tube part.

[0016]

[Example] The top view showing the catheter 30 which drawing 4 (A) requires for the 1st example of this invention, the top view in which drawing 4 (B) exfoliates and shows a part of outer tube part of this catheter 30, drawing 5 (A), and (B) are the top views showing the

Appendix C

manufacture process of this catheter 30.

[0017] a catheter 30 is shown in drawing 4 (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- smallness -- a point 31 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 32 is really formed in shaft orientations. between the flexible inner tube part 33 in the body section 31 if it is in the above-mentioned catheter 30, and the flexible outer tube parts 34 -- much more -- since -- the becoming reinforcement layer 35 is infixed and the point 32 is formed according to the unification condition of an inner tube part 33 and an outer tube part 34. Here, the reinforcement layer 35 is formed from wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side). The edge by the side of the point 32 of wire layer 35B is pasted up on the inner tube part 33.

[0018] While according to the above-mentioned catheter 30 the body section 31 and a point 32 are really formed, torsional rigidity has flexibility in a point 32 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 31 and the point 32, it becomes possible to form the bore which becomes size comparatively. If it is in the above-mentioned catheter 30 especially, by wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side) Since the reinforcement layer 35 was formed, while making quick responsibility of the point [as opposed to rotation of the body section 31 for change of the torsional rigidity of the body section 31 and a point 32] 32 as a loose thing It becomes possible to prevent that sudden a point 32 bends to the body section 31, and to prevent lock out generating of a catheter building envelope based on bending. Moreover, if it was in the above-mentioned catheter 30, since the edge by the side of the point 32 of wire layer 35B was pasted up on the inner tube part 33, it becomes possible to prevent the exfoliation from the inner tube part 33 of wire layer 35B in a manufacture phase.

[0019] Next, the manufacture approach of the above-mentioned catheter 30 is explained. First, extrusion molding of the flexible inner tube part 33 is carried out. Next, as shown in drawing 5 (A), the reinforcement layer 35 is continuously formed further in the top face of an inner tube part 33. here -- wire layer 35A with the eye of a network dense [the reinforcement layer 35] (for example, pitch P1 = 1mm), and the eye of a network -- ** (for example, pitch P2 = 10mm) -- wire layer 35B is formed by turns. Next, after pasting up with adhesives the edge of wire layer 35B of the fixed section which should be removed on an inner tube part 33, a part of abbreviation center section of the above-mentioned wire layer 35B is removed as shown in drawing 5 (B). Next, extrusion molding of the flexible outer tube part 34 is carried out to the top face of an inner tube part 33 and the wire layers 35A and 35B. Next, abbreviation pars intermedia X1 of a part with wire layer 35A Abbreviation pars intermedia X2 of a part without the reinforcement layer 35 The catheter 30 which cuts, makes a part with the wire layers 35A and 35B the body section 31, and uses a part without the reinforcement layer 35 as a point 32 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 35, and a part without the reinforcement layer 35, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 35 and the pars intermedia of a part without the reinforcement layer 35"] was provided here, if it was in this example etc., and it is a catheter 30 about the reinforcement layer 35. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 30.

Appendix C

[0020] The top view showing the catheter 40 which drawing 6 (A) requires for the 2nd example of this invention, the top view in which drawing 6 (B) exfoliates and shows a part of outer tube part of this catheter 40, drawing 7 (A), and (B) are the top views showing the manufacture process of this catheter 40.

[0021] a catheter 40 is shown in drawing 6 (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- size -- the body section 41 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 42 is really formed in shaft orientations. between the flexible inner tube part 43 in the body section 41 if it is in the above-mentioned catheter 40, and the flexible outer tube parts 44 -- much more -- since -- the becoming reinforcement layer 45 is infixed and the point 42 is formed in an inner tube part 43 according to the unification condition of an outer tube part 44. Here, the reinforcement layer 45 is formed from wire layer 45A by which the anti-point 42 side (end face side) in the body section 41 was knit, and wire layer 45B by which the point 42 side in the body section 41 is not knit. The edge by the side of the point 42 of wire layer 45B is pasted up on the inner tube part 43. Wire layer 45B which is not knit is prepared in a catheter shaft and parallel as drawing 7.

[0022] While according to the above-mentioned catheter 40 the body section 41 and a point 42 are really formed, torsional rigidity has flexibility in a point 42 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 41 and the point 42, it becomes possible to form the bore which becomes size comparatively. Moreover, like said catheter 30, while the above-mentioned catheter 40 makes quick responsibility of the point [as opposed to rotation of the body section 41 for change of the torsional rigidity of the body section 41 and a point 42] 42 as a loose thing, prevention of sudden a point 42 bending to the body section 41 of it is attained. Moreover, if it was in the above-mentioned catheter 40, since the edge by the side of the point 42 of wire layer 45B was pasted up on the inner tube part 43, it becomes possible to prevent the exfoliation from the inner tube part 43 of the edge of wire layer 45B in a manufacture phase.

[0023] Next, the manufacture approach of the above-mentioned catheter 40 is explained. First, extrusion molding of the flexible inner tube part 43 is carried out. Next, on an inner tube part 43, as shown in drawing 7 (A), the reinforcement layer 45 is formed further continuously. Here, wire layer 45A by which the reinforcement layer 45 was knit, and reinforcement layer 45B which is not knit are formed by turns. Next, after pasting up with adhesives the edge of wire layer 45B of the fixed section which should be removed on an inner tube part 43, a part of abbreviation center section of the above-mentioned wire layer 45B is removed as shown in drawing 7 (B). Next, extrusion molding of the outer tube part 44 is carried out to the top face of an inner tube part 43 and the wire layers 45A and 45B. Next, abbreviation pars intermedia X1 of a part with wire layer 45A Abbreviation pars intermedia X2 of a part without the reinforcement layer 45 The catheter 40 which cuts, makes a part with the wire layers 45A and 45B the body section 41, and uses a part without the reinforcement layer 45 as a point 42 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 45, and a part without the reinforcement layer 45, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 45 and the pars intermedia of a part without the reinforcement layer 45"] was provided here, if it was in this example etc., and it is a catheter 40 about the reinforcement layer 45. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 40.

Appendix C

[0024]

[Effect of the Invention] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point according to this invention as mentioned above. While being able to form the bore which becomes size comparatively and making quick further responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing The catheter which can prevent that sudden a point bends to the body section can be offered.

PRIOR ART

[Description of the Prior Art] The catheter 1 as shown in drawing 1 is led to a guidewire etc., and is inserted into coelomata, such as a blood vessel, and attainment of it to the target part is enabled, the direction of the tip being controlled.

[0003] So, this catheter 1 is required to have the torsional rigidity which becomes size so that it may be possible to twist the base of the body section 2 and to orient that point 3. moreover, the point 3 -- the purpose part -- insertion -- it is possible to give an easy configuration easily, and flexibility is required of a point 3 so that the point 3 at the time of insertion may deform easily along with insertion path change of a blood vessel etc. and damage may not be done to walls, such as a blood vessel.

[0004] drawing 2 -- a point -- flexibility -- having -- and -- size -- the conventional catheter 4 which comes to have torsional rigidity is shown -- it is a fracture Fig. a part. The catheter 4 forms the body section 8 which is torsional rigidity and which becomes size by infixing the wire layer 7 between the flexible inner tube part 5 and the flexible outer tube part 6. Furthermore, the comparatively flexible point 9 is connected to the edge at which this catheter 4 removed the outer tube part 6 of the above-mentioned body section 8 in part.

[0005] drawing 3 -- a point -- flexibility -- having -- and -- size -- other conventional catheters 10 which come to have torsional rigidity are shown -- it is a fracture Fig. a part. After this catheter 10 had the 1st wire layer 12 formed from the end face of the flexible inner tube part 11 to tip this side, and it turns it up from that tip this side and it has the 2nd wire layer 13 again formed to a end face, it is having the flexible outer tube part 14 covered by the top face of an inner tube part 11 and both the wire layers 12 and 13.

EFFECT OF THE INVENTION

[Effect of the Invention] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point according to this invention as mentioned above, The bore which becomes size comparatively can be formed, and further, while making quick responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing, the catheter which can prevent that sudden a point bends to the body section can be offered.

Appendix C

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention] However, if it is in the above-mentioned catheter 4, a level difference is produced in the connection of the body section 8 and a point 9, it is difficult to perform insertion to a blood vessel etc. smoothly, and there is a possibility of producing a thrombus. Moreover, there is a possibility of producing balking among both, according to the faulty connection of the body section 8 and a point 9.

[0007] Moreover, since the reinforcement layer which consists of the 1st wire layer 12 and the 2nd wire layer 13 of a bilayer between the inner tube parts 11 and outer tube parts 14 from which the above-mentioned catheter 10 constitutes the body section is infixed, a catheter bore serves as smallness under the predetermined catheter outer diameter in which the thickness of a reinforcement layer becomes settled with insertion way bores, such as a blood vessel in which a large next door and a catheter are inserted. Moreover, since the thickness of the above-mentioned reinforcement layer is size, the level difference which comes size comparatively between the catheter outer diameter of the body section and the catheter outer diameter of a point is produced, and it becomes difficult to perform insertion to a blood vessel etc. Moreover, the above-mentioned catheter 10 is the top face of the inner tube part 11 which constitutes the body section, since it forms by turning up the 1st wire layer 12 and the 2nd wire layer 13, cannot form the whole continuously and cannot obtain the base material for catheters.

[0008] Moreover, while carrying out a loose thing for change of the torsional rigidity of the body section and a point and making quick responsibility of the point to rotation of the body section in order to improve the insertion workability into a blood vessel coelome if it is in a catheter, to enable prevention of sudden a point bending to the body section is desired.

[0009] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point, this invention While being able to form the bore which becomes size comparatively and making quick further responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing The purpose is carried out for offering the catheter which can prevent that sudden a point bends to the body section.

MEANS

[Means for Solving the Problem] This invention according to claim 1 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer knit by ** by the side of the tip in the wire layer knit densely and the body section by the side of the end face in the body section.

[0011] This invention according to claim 2 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since --

Appendix C

further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer in which the end face side in the body section was knit, and a wire layer in which the tip side in the body section is not knit.

[0012] between inner tube parts and outer tube parts -- much more -- since -- the becoming reinforcement layer is infixed, this point does not have the above-mentioned reinforcement layer, but the edge by the side of the tip of said reinforcement layer is being further fixed to the inner tube part. [in / this invention according to claim 3 is a catheter which consists of an inner tube part which results at a tip from an end face, and an outer tube part which covers this inner tube part, and this catheter has a point and the body section, and / this body section] In addition, "immobilization" said here shall paste up the edge by the side of the tip of a reinforcement layer on an inner tube part with adhesives, and also laying under the inner tube welding and the wire layer which is a reinforcement layer further at an inner tube, applying heat shall include it.

OPERATION

[Function] According to this invention, there is the operation effectiveness of the following ** - **.

** between inner tube parts and outer tube parts -- much more -- since -- since the becoming reinforcement layer is infixed and it was made for this point not to have the above-mentioned reinforcement layer, while the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and an outer diameter is equalized by the body section and the point -- comparatively -- size -- it becomes possible to form a bore. [in / a catheter has a point and the body section and / this body section]

[0014] ** Since the reinforcement layer was constituted from two steps of what is not knit with two steps or the knit thing of ** as it is dense, while making quick responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing, it becomes possible to prevent that sudden a point bends to the body section.

[0015] ** The edge by the side of the tip of a reinforcement layer becomes possible [preventing the exfoliation from the inner tube part of the reinforcement layer edge in a manufacture phase] by coming to be fixed to an inner tube part.

EXAMPLE

[Example] The top view showing the catheter 30 which drawing 4 (A) requires for the 1st example of this invention, the top view in which drawing 4 (B) exfoliates and shows a part of outer tube part of this catheter 30, drawing 5 (A), and (B) are the top views showing the manufacture process of this catheter 30.

[0017] a catheter 30 is shown in drawing 4 (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- smallness -- a point 31 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 32 is really formed in shaft orientations. between the flexible inner tube part 33 in the body section 31 if it is in the above-mentioned catheter 30, and the flexible outer tube parts 34 -- much more -- since -- the becoming reinforcement layer 35 is infixed and the point 32 is formed according to the unification condition of an inner tube part 33 and an outer

Appendix C

tube part 34. Here, the reinforcement layer 35 is formed from wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side). The edge by the side of the point 32 of wire layer 35B is pasted up on the inner tube part 33.

[0018] While according to the above-mentioned catheter 30 the body section 31 and a point 32 are really formed, torsional rigidity has flexibility in a point 32 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 31 and the point 32, it becomes possible to form the bore which becomes size comparatively. If it is in the above-mentioned catheter 30 especially, by wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side) Since the reinforcement layer 35 was formed, while making quick responsibility of the point [as opposed to rotation of the body section 31 for change of the torsional rigidity of the body section 31 and a point 32] 32 as a loose thing It becomes possible to prevent that sudden a point 32 bends to the body section 31, and to prevent lock out generating of a catheter building envelope based on bending. Moreover, if it was in the above-mentioned catheter 30, since the edge by the side of the point 32 of wire layer 35B was pasted up on the inner tube part 33, it becomes possible to prevent the exfoliation from the inner tube part 33 of wire layer 35B in a manufacture phase.

[0019] Next, the manufacture approach of the above-mentioned catheter 30 is explained. First, extrusion molding of the flexible inner tube part 33 is carried out. Next, as shown in drawing 5 (A), the reinforcement layer 35 is continuously formed further in the top face of an inner tube part 33. here -- wire layer 35A with the eye of a network dense [the reinforcement layer 35] (for example, pitch P1 = 1mm), and the eye of a network -- ** (for example, pitch P2 = 10mm) -- wire layer 35B is formed by turns. Next, after pasting up with adhesives the edge of wire layer 35B of the fixed section which should be removed on an inner tube part 33, a part of abbreviation center section of the above-mentioned wire layer 35B is removed as shown in drawing 5 (B). Next, extrusion molding of the flexible outer tube part 34 is carried out to the top face of an inner tube part 33 and the wire layers 35A and 35B. Next, abbreviation pars intermedia X1 of a part with wire layer 35A Abbreviation pars intermedia X2 of a part without the reinforcement layer 35 The catheter 30 which cuts, makes a part with the wire layers 35A and 35B the body section 31, and uses a part without the reinforcement layer 35 as a point 32 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 35, and a part without the reinforcement layer 35, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 35 and the pars intermedia of a part without the reinforcement layer 35"] was provided here, if it was in this example etc., and it is a catheter 30 about the reinforcement layer 35. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 30.

[0020] The top view showing the catheter 40 which drawing 6 (A) requires for the 2nd example of this invention, the top view in which drawing 6 (B) exfoliates and shows a part of outer tube part of this catheter 40, drawing 7 (A), and (B) are the top views showing the manufacture process of this catheter 40.

[0021] a catheter 40 is shown in drawing 6 (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- size -- the body section 41 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 42 is really formed in shaft orientations. between the flexible inner tube

Appendix C

part 43 in the body section 41 if it is in the above-mentioned catheter 40, and the flexible outer tube parts 44 -- much more -- since -- the becoming reinforcement layer 45 is infixed and the point 42 is formed in an inner tube part 43 according to the unification condition of an outer tube part 44. Here, the reinforcement layer 45 is formed from wire layer 45A by which the anti-point 42 side (end face side) in the body section 41 was knit, and wire layer 45B by which the point 42 side in the body section 41 is not knit. The edge by the side of the point 42 of wire layer 45B is pasted up on the inner tube part 43. Wire layer 45B which is not knit is prepared in a catheter shaft and parallel as drawing 7.

[0022] While according to the above-mentioned catheter 40 the body section 41 and a point 42 are really formed, torsional rigidity has flexibility in a point 42 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 41 and the point 42, it becomes possible to form the bore which becomes size comparatively. Moreover, like said catheter 30, while the above-mentioned catheter 40 makes quick responsibility of the point [as opposed to rotation of the body section 41 for change of the torsional rigidity of the body section 41 and a point 42] 42 as a loose thing, prevention of sudden a point 42 bending to the body section 41 of it is attained. Moreover, if it was in the above-mentioned catheter 40, since the edge by the side of the point 42 of wire layer 45B was pasted up on the inner tube part 43, it becomes possible to prevent the exfoliation from the inner tube part 43 of the edge of wire layer 45B in a manufacture phase.

[0023] Next, the manufacture approach of the above-mentioned catheter 40 is explained. First, extrusion molding of the flexible inner tube part 43 is carried out. Next, on an inner tube part 43, as shown in drawing 7 (A), the reinforcement layer 45 is formed further continuously. Here, wire layer 45A by which the reinforcement layer 45 was knit, and reinforcement layer 45B which is not knit are formed by turns. Next, after pasting up with adhesives the edge of wire layer 45B of the fixed section which should be removed on an inner tube part 43, a part of abbreviation center section of the above-mentioned wire layer 45B is removed as shown in drawing 7 (B). Next, extrusion molding of the outer tube part 44 is carried out to the top face of an inner tube part 43 and the wire layers 45A and 45B. Next, abbreviation pars intermedia X1 of a part with wire layer 45A Abbreviation pars intermedia X2 of a part without the reinforcement layer 45 The catheter 40 which cuts, makes a part with the wire layers 45A and 45B the body section 41, and uses a part without the reinforcement layer 45 as a point 42 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 45, and a part without the reinforcement layer 45, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 45 and the pars intermedia of a part without the reinforcement layer 45"] was provided here, if it was in this example etc., and it is a catheter 40 about the reinforcement layer 45. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 40.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1] Drawing 1 is the top view showing a common catheter.

[Drawing 2] drawing 2 shows the catheter concerning the conventional example -- it is a fracture

Appendix C

Fig. a part.

[Drawing 3] drawing 3 shows the catheter concerning other conventional examples -- it is a fracture Fig. a part.

[Drawing 4] They are the top view showing the catheter which drawing 4 (A) requires for the 1st example of this invention, and the top view in which drawing 4 (B) exfoliates and shows a part of outer tube part of this catheter.

[Drawing 5] Drawing 5 (A) and (B) are the top views showing the manufacture process of this catheter.

[Drawing 6] They are the top view showing the catheter which drawing 6 (A) requires for the 2nd example of this invention, and the top view in which drawing 6 (B) exfoliates and shows a part of outer tube part of this catheter.

[Drawing 7] Drawing 7 (A) and (B) are the top views showing the manufacture process of this catheter.

[Description of Notations]

30 40 Catheter

31 41 Body section

32 42 Point

33 43 Inner tube part

34 44 Outer tube part

35 45 Reinforcement layer

35A, 35B, 45A, 45B Wire layer

[Translation done.]

Appendix C